1,947	1,962	1,851	1,821	1,825		7,296	1,709	
5,881	5,925	5,590	5,501	5,512	5,435	22,038	5,162	4,997
0	0	0	0	0	0	0	0	0
120,539	121,438	114,582	112,743	112,969	111,404	451,699	105,796	102,421
0	0	0	0	0	0	0	0	0
4,430	4,463	4,211	4,143	4,152	4,094	16,601	3,888	3,764
3,498	3,524	3,325	3,272	3,278	3,233	13,108	3,070	2,972
91,255	91,936	86,745	85,353	85,524	84,340	341,962	80,093	77,539
75	76	71	70	70	69	281	66	64
156,873	158,044	149,120	146,727	147,022	144,985	587,854	137,685	133,294
90	91	86	84	84	83	337	79	76
8,145	8,206	7,742	7,618	7,634	7,528	30,522	7,149	6,921
180	181	171	168	169	166	675	158	153
6,625	6,674	6,298	6,197	6,209	6,123	24,826	5,815	5,629
0	0	0	0	0	0	0	0	0
6,648	6,698	6,319	6,218	6,231	6,144	24,912	5,835	5,649
98	99	93	92	92	91	367	86	83
0	0	0	0	0	0	0	0	0
60	60	57	56	56	55	225	53	51
6,545	6,594	6,222	6,122	6,134	6,049	24,526	5,744	5,561
23,404	23,579	22,247	21,890	21,934	21,630	87,702	20,541	19,886
0	0	0	0	0	0	0	0	0
360	363	342	337	337	333	1,349	316	306
18,581	18,720	17,663	17,379	17,414	17,173	69,629	16,308	15,788
361,628	364,326	343,756	338,240	338,919	334,223	1,355,138	317,396	307,272
3,038	3,061	2,888	2,842	2,847	2,808	11,384	2,666	2,581
372,650	375,431	354,234	348,549	349,248	344,410	1,396,441	327,070	316,638
2,035	2,050	1,934	1,903	1,907	1,881	7,626	1,786	1,729
24,265	24,446	23,066	22,696	22,741	22,426	90,929	21,297	20,618
30	30	29	28	28	28	112	26	25
12,429	12,522	11,815	11,625	11,648	11,487	46,576	10,909	10,561
16,876	17,002	16,042	15,785	15,816	15,597	63,240	14,812	14,339
0	0	0	0	0	- 0	0	0	0
1,760	1,773	1,673	1,646	1,649	1,627	6,595	1,545	1,495
81	82	77	76	76	75	304	71	69
8,917	8,984	8,476	8,340	8,357	8,241	33,415	7,826	7,577
0	0	0	0	0	0	0	0	0
112,468	113,307	106,910	105,194	105,405	103,945	421,454	98,712	95,563
45	45	43	42	42	42	169	39	38
5,890	5,934	5,599	5,509	5,520	5,444	22,072	5,170	5,005
1,456	1,467	1,384	1,362	1,365	1,346	5,456	1,278	1,237
19,692	19,839	18,719	18,418	18,455	18,200	73,792	17,283	16,732
237	239	225	222	222	219	888	208	201
32,614	32,857	31,002	30,505	30,566	30,142	122,215	28,625	
1	1	1	1	1	1	4	20,023	27,712
9,540	9,611	9,069		8,941				9 106
	20,341		8,923	18,922	8,817	35,749	8,373	8,106
20,190		19,192	18,884		18,660	75,659	17,720	17,155
159,890	161,083	151,988	149,549	149,849	147,773	599,160	140,333	135,857
7,875	7,934	7,486	7,366	7,380	7,278	29,510	6,912	6,691
136,306	137,323	129,570	127,490	127,746	125,977	510,783	119,634	115,818
3,509	3,535	3,336	3,282	3,289	3,243	13,149	3,080	2,982
28,745	28,959	27,324	26,886	26,940	26,567	107,717	25,229	24,424

76	78	334	82	83	83	85	90	89
1,229	1,269	5,419	1,336	1,355	1,352	1,375	1,457	1,446
887	916	3,912	965	978	976	992	1,052	1,044
0	0	0	0	0	0	0	0	0
8,732	9,020	38,511	9,498	9,632	9,612	9,769	10,354	10,277
34	35	150	37	37	37	38	40	40
16,631	17,179	73,346	18,090	18,344	18,307	18,606	19,719	19,573
51	53	225	55	56	56	57	60	60
892	922	3,935	970	984	982	998	1,058	1,050
91,497	94,512	403,523	99,523	100,921	100,719	102,361	108,487	107,683
######	######	4,884,055	#####	######	######	######	1,313,069	1,303,344
######	######	4,796,255	######	######	######	######	1,289,465	1,279,914
31,778	32,825	140,150	34,566	35,051	34,981	35,552	37,679	37,400
13,068		57,634	14,214	14,414	14,385	14,620	15,495	15,380
81,575		359,766	88,731	89,977	89,797	91,261	96,722	96,006
158,878		700,686	172,813				188,378	186,983
37,733	38,976	166,411	41,043	41,619	41,536	42,213	44,739	44,408
958	989	4,223	1,042	1,056	1,054	1,071	1,135	1,127
44,430		195,944	48,326	49,005			52,679	52,289
1,028	1,062	4,534	1,118	1,134		1,150	1,219	1,210
72,388	74,773	319,246	78,737	79,843		80,983	85,829	85,193
743	767	3,275	808	819	817	831	881	874
	3,594	15,345	3,785	3,838		3,893	4,126	4,095
		12,969				3,290	3,487	3,461
84,384	87,164	372,151	91,785	93,074	92,888	94,403	100,052	99,311
13	13	56	14	14	14	14	15	15
129,388	133,651	570,628	140,736	142,713	142,428	144,751	153,412	152,276
168	174	742	183	186	185	188	199	198
3,943	4,072	17,388	4,288	4,349	4,340	4,411	4,675	4,640
3,186	3,291	14,052	3,466	3,515	3,507	3,565	3,778	3,750
33,456	34,558	147,547	36,390	36,901	36,827	37,428	39,668	39,374
	850	3,627	895	907	905	920	975	968
823			59,283	60,116	59,995	60,974	64,623	64,144
54,503	56,298 703	240,368		751	749	761	807	801
681		3,002	740					
7,762	8,018	34,232	8,443	8,561	8,544	8,684	9,203	9,135
336	347	1,480	365	370	369	375	398	395
4,610	4,761	20,329	5,014	5,084	5,074	5,157	5,465	5,425
5,720	5,909	25,227	6,222	6,309	6,297	6,399	6,782	6,732
408	421	1,799	444	450	449	456	484	480
3,648	3,768	16,087	3,968	4,023	4,015	4,081	4,325	4,293
61,417	63,441	270,864	66,804	67,743	67,607	68,710	72,821	72,282
326	337	1,439	355	360	359	365	387	384
68,411	70,665	301,708	74,412	75,457	75,306	76,534	81,114	80,513
200	206	881	217	220	220	223	237	235
8,821	9,111	38,901	9,594	9,729	9,710	9,868	10,458	10,381
538	556	2,372	585	593	592	602	638	633
13,943	14,403	61,494	15,166	15,379	15,349	15,599	16,532	16,410
15,179	15,679	66,942	16,510	16,742	16,709	16,981	17,997	17,864
1,020	1,053	4,497	1,109	1,125	1,122	1,141	1,209	1,200
720	743	3,174	783	794	792	805	853	847
20,926	21,616	92,289	22,762	23,081	23,035	23,411	24,812	24,628
443	457	1,952	482	488	487	495	525	521

41,383	42,746	182,506	45,012	45,645	45,553	46,296	49,066	48,703
166	171	731	180	183	182	185	196	195
3,110	3,212	13,715	3,383	3,430	3,423	3,479	3,687	3,660
22,866	23,619	100,844	24,872	25,221	25,171	25,581	27,112	26,911
436,294	450,669	1,924,151	474,561	481,228	480,264	488,097	517,304	513,473
399,879	413,054	1,763,555	434,953	441,063	440,180	447,359	474,129	470,617
36,549	37,754	161,191	39,755	40,314	40,233	40,889	43,336	43,015
1,444	1,491	6,367	1,570	1,592	1,589	1,615	1,712	1,699
41,471	42,837	182,896	45,108	45,742	45,650	46,395	49,171	48,807
216	223	952	235	238	238	241	256	254
56,559	58,422	249,437	61,520	62,384	62,259	63,274	67,061	66,564
2,817	2,910	12,422	3,064	3,107	3,101	3,151	3,340	3,315
3,739	3,863	16,492	4,067	4,125	4,116	4,184	4,434	4,401
58,703	60,637	258,891	63,851	64,748	64,619	65,673	69,603	69,087
1,098	1,134	4,842	1,194	1,211	1,208	1,228	1,302	1,292
76,250	78,762	336,278	82,938	84,103	83,934	85,303	90,408	89,738
4,201		18,527	4,569	4,634	4,624	4,700	4,981	4,944
4,690	4,845	20,685	5,102	5,173	5,163	5,247	5,561	5,520
779	805	3,436	848	859	858	872	924	917
18,686	19,301	82,407	20,324	20,610	20,569	20,904	22,155	21,991
25	26	112	28	28	28	29	30	30
54,397	56,190	239,904	59,168	60,000	59,879	60,856	64,498	64,020
0	0	0	0	00,000	0	00,030	0	0
2,226	2,300	9,818	2,421	2,455	2,451	2,491	2,640	2,620
2,676	2,764	11,800	2,910	2,951	2,945	2,993	3,172	3,149
44,457	45,921	196,064	48,356	49,035	48,937	49,735	52,711	52,321
0	0	0	0	0	0	0	0	0
75,841	78,340	334,475	82,493	83,652	83,484	84,846	89,923	89,257
75,041	0	0	02,493	03,032	03,404	04,040	09,923	09,237
2,829	2,923	12,479	3,078	3,121	3,115	3,165	3,355	3,330
2,180	2,252	9,616	2,372	2,405	2,400	2,439	2,585	2,566
	87,966		92,630	93,931		95,272	100,973	
85,160	160	375,576			93,743			100,225
155	132,883	682	168	171	170	173	183	182
128,644	199	567,349 851	139,928	141,893 213	141,609	143,919	152,531	151,401
193		66,328	210		212	216	229	227
15,040	15,535		16,359	16,588	16,555	16,825	17,832	17,700
828	856	3,654	901	914	912	927	982	975
39,734	41,043	175,236	43,219	43,826	43,739	44,452	47,112	46,763
333	344	1,469	362	367	367	373	395	392
72,151	74,528	318,200	78,479	79,582	79,422	80,718	85,548	84,914
583	602	2,571	634	643	642	652	691	686
1,020	1,053	4,497	1,109	1,125	1,122	1,141	1,209	1,200
306	316	1,349	333	337	337	342	363	360
10,042	10,373	44,286	10,922	11,076	11,054	11,234	11,906	11,818
71	74	315	78	79	79	80	85	84
13,960	14,420	61,565	15,184	15,397	15,366	15,617	16,552	16,429
2,447	2,528	10,792	2,662	2,699	2,694	2,738	2,901	2,880

DC, HI, MI, MN 19,441 304,702 4,408

530,178
3,432
34,460

DE, LA,	MD
	42,880
	637,860
	536,295

-28.9%	-26.0%	-28.7%	-90.0%	-12.8%		-3.9%	0.1%
Q1 2013	Q4 2012	Q3 2012	Q2 2012	Q1 2012	CY2011	Q4 2011	Q3 2011
28	39	53	74	740	3,525	848	883
609	856	1,156	1,621	16,167	77,005	18,535	19,297
581	816	1,103	1,546	15,420	73,446	17,678	18,405
3	4	6	8	83	397	96	100
8	11	15	21	214	1,019	245	255
325	456	617	865	8,624	41,076	9,887	10,293
5,627	7,909	10,687	14,989	149,467	711,909	171,352	178,398
42	60	80	113	1,125	5,358	1,290	1,343
5,556	7,809	10,552	14,800	147,578	702,911	169,187	176,143
36	50	68	96	952	4,536	1,092	1,137
469	660	891	1,250	12,465	59,372	14,290	14,878
C	0	0	0	0	0	0	0
3,181	4,471	6,042	8,474	84,501	402,477	96,874	100,857
2	2	3	4	43	204	49	51
3,031	4,260	5,756	8,074	80,508	383,459	92,296	96,091
C	0	0	0	0	0	0	0
C	0	0	0	0	0	0	0
1,368	1,923	2,598	3,644	36,332	173,049	41,652	43,364
26,120	36,712	49,606	69,577	693,791	3,304,507	795,376	828,079
114	161	217	305	3,039	14,475	3,484	3,627
20,831	29,278	39,560	55,487	553,293	2,635,318	634,306	660,387

153	216	292	409	4,077	19,419	4,674	4,866
808	1,135	1,534	2,152	21,459	102,207	24,601	25,612
107	150	202	284	2,832	13,487	3,246	3,380
2,239	3,147	4,252	5,964	59,471	283,259	68,179	70,982
2	3	5	6	64	306	74	77
2,251	3,164	4,275	5,996	59,794	284,797	68,549	71,368
0	0	0	0	0	0	0	0
91	128	173	242	2,417	11,511	2,771	2,885
331	465	629	882	8,791	41,871	10,078	10,492
4,565	6,416	8,670	12,160	121,256	577,539	139,010	144,726
0	1	1	1	11	54	13	14
4,515	6,345	8,574	12,026	119,914	571,149	137,472	143,125
240	337	455	638	6,363	30,305	7,294	7,594
30	42	57	80	796	3,789	912	950
570	801	1,082	1,518	15,139	72,108	17,356	18,070
17	24	32	45	451	2,149	517	539
419	589	795	1,116	11,124	52,981	12,752	13,277
0	0	0	0	0	0	0	0
45	63	86	120	1,198	5,705	1,373	1,430
80	112	152	213	2,124	10,115	2,435	2,535
	2,321	3,136	4,399	43,862	208,913	50,284	52,352
1,651	17	23	32	322	1,535	369	385
1,897	2,667	3,603	5,054	50,396	240,033	57,775	60,150
11	16	21	30	297	1,416	341	355
116	163	220	309	3,083	14,686	3,535	3,680
							22,900
722	1,015	1,372	1,924	19,187	91,385	21,996	
12,236	17,198	23,238	32,593	325,006	1,547,994	372,593	387,913
209	294	398	558	5,562	26,492	6,377	6,639
11,497	16,159	21,834	30,624	305,371	1,454,473	350,083	364,478
180	253	342	479	4,781	22,771	5,481	5,706
806	1,133	1,530	2,147	21,405	101,952	24,539	25,548
29	41	55	77	768	3,657	880	916
906	1,273	1,721	2,413	24,064	114,614	27,587	28,721
8	11	15	22	215	1,022	246	256
1,181	1,660	2,243	3,145	31,365	149,388	35,957	37,435
6	9	12	17	171	815	196	204
188	264	357	501	4,998	23,803	5,729	5,965
1	1	2	2	21	102	25	26
15	21	29	40	400	1,905	459	477
1	1	1	2	16	75	18	19
10	15	20	28	276	1,314	316	329
19	27	36	50	501	2,387	575	598
461	648	876	1,229	12,251	58,353	14,045	14,623
0	0	0	0	0	0	0	0
7,617	10,707	14,467	20,291	202,332	963,701	231,957	241,495
2	2	3	4	43	204	49	51
470	661	893	1,252	12,486	59,470	14,314	14,903
24	34	46	65	644	3,066	738	768
645	907	1,225	1,718	17,134	81,609	19,643	20,451
1,075	1,511	2,042	2,864	28,554	136,003	32,735	34,081
1	1	2	2	22	105	25	26
136	191	258	362	3,607	17,182	4,136	4,306

882	1,240	1,676	2,351	23,440	111,643	26,872	27,977
9,289	13,056	17,641	24,743	246,728	1,175,160	282,854	294,484
31	43	58	82	813	3,874	933	971
7,714	10,841	14,649	20,547	204,883	975,850	234,882	244,539
35	50	67	94	940	4,479	1,078	1,122
691	972	1,313	1,842	18,366	87,477	21,055	21,921
197	277	374	524	5,228	24,900	5,993	6,240
2,864	4,025	5,438	7,628	76,059	362,267	87,196	90,781
130	182	247	346	3,448	16,421	3,952	4,115
3,588	5,044	6,815	9,559	95,315	453,981	109,271	113,764
116	163	220	308	3,071	14,628	3,521	3,666
539	757	1,023	1,435	14,305	68,132	16,399	17,073
72	102	138	193	1,926	9,171	2,208	2,298
2,107	2,962	4,002	5,613	55,970	266,583	64,165	66,803
1	1	1	1	14	68	16	17
2,123	2,984	4,033	5,656	56,400	268,631	64,658	67,316
242	340	459	643	6,416	30,560	7,356	7,658
44	62	84	118	1,176	5,603	1,349	1,404
150	211	285	399	3,983	18,971	4,566	4,754
46	65	88	123	1,228	5,847	1,407	1,465
2,458	3,455	4,669	6,548	65,295	310,997	74,855	77,933
52	73	99	138	1,380	6,574	1,582	1,647
0	0	0	0	0	0	0	0
401	563	761	1,067	10,639	50,676	12,197	12,699
8,660	12,172	16,446	23,068	230,021	1,095,582	263,700	274,543
3	4	5	8	75	357	86	89
6,825	9,593	12,962	18,181	181,292	863,487	207,836	216,382
0,023	6	8	11	107	509	123	128
428	601	813	1,140	11,364	54,125	13,028	13,563
79	111	150	210	Control Control of the Control of th	9,969	2,400	2,498
				2,093	125,103	30,112	31,350
989	1,390	1,878	2,634	26,266	0	0	0
	2 626		700 1 100 100 100 100	49,819			192020000000000000000000000000000000000
1,876	2,636	3,562	4,996		237,286	57,113 0	59,462
177	0	0	472	4 705	0	5,394	
177	249	336	472	4,705	22,411		5,616
670	942	1,273	1,786	17,806	84,811	20,414	21,253
6,809	9,570	12,931	18,137	180,855	861,406	207,335	215,860
140	197	266	374	3,725	17,742	4,270	4,446
5,671	7,971	10,771	15,107	150,643	717,508	172,700	179,801
17	23	31	44	440	2,095	504	525
633	890	1,202	1,686	16,816	80,095	19,278	20,071
24	34	46	64	640	3,049	734	764
388	545	736	1,033	10,299	49,052	11,807	12,292
1	2	2	3	32	153	37	38
4,789	6,731	9,094	12,756	127,195	605,825	145,818	151,814
271	380	514	721	7,188	34,238	8,241	8,580
439	617	833	1,169	11,655	55,511	13,361	13,911
7,435	10,450	14,121	19,806	197,493	940,655	226,410	235,720
101	142	191	268	2,676	12,744	3,067	3,193
10,566	14,850	20,066	28,144	280,637	1,336,664	321,727	334,956
92	129	175	245	2,447	11,654	2,805	2,920
761	1,069	1,445	2,027	20,211	96,264	23,170	24,123

52	73	99	139	1,388	6,611	1,591	1,657
158	222	300	420	4,193	19,969	4,807	5,004
0	0	0	0	0	0	0	0
3,235	4,547	6,144	8,618	85,934	409,299	98,516	102,567
0	0	0	0	0	0	0	0
119	167	226	317	3,158	15,042	3,621	3,769
94	132	178	250	2,494	11,878	2,859	2,976
2,449	3,443	4,652	6,524	65,057	309,863	74,582	77,649
2	3	4	5	53	255	61	64
4,210	5,918	7,996	11,216	111,836	532,674	128,212	133,483
2	3	5	6	64	306	74	77
219	307	415	582	5,807	27,657	6,657	6,931
5	7	9	13	128	611	147	153
178	250	338	474	4,723	22,496	5,415	5,637
0	0	0	0	0	0	0	0
178	251	339	475	4,739	22,574	5,433	5,657
3	4	5	7	70	333	80	83
0	0	0	0	0	0	0	0
2	2	3	4	43	204	49	51
176	247	334	468	4,666	22,224	5,349	5,569
628	883	1,193	1,673	16,685	79,470	19,128	19,914
0	0	0	0	, 0	0	, 0	0
10	14	18	26	257	1,222	294	306
499	701	947	1,328	13,247	63,093	15,186	15,811
9,706	13,642	18,433	25,855	257,808	1,227,934	295,557	307,709
82	115	155	217	2,166	10,316	2,483	2,585
10,002	14,058	18,995	26,643	265,666	1,265,360	304,565	317,088
55	77	104	145	1,451	6,910	1,663	1,732
651	915	1,237	1,735	17,299	82,394	19,832	20,647
1	1	2	2	21	102	25	26
334	469	634	889	8,861	42,204	10,158	10,576
453	637	860	1,207	12,031	57,304	13,793	14,360
433	0	0	0	0	0	0	0
47	66	90	126	1,255	5,976	1,438	1,498
2	3	4	6	58	275	7 200	69
239	336	455	638	6,357	30,278	7,288	7,587
0	0	0	0	0	0	0	0
3,019	4,243	5,733	8,041	80,180	381,893	91,920	95,699
1	2	2	3	32	153	37	38
158	222	300	421	4,199	20,000	4,814	5,012
39	55	74	104	1,038	4,944	1,190	1,239
529	743	1,004	1,408	14,039	66,866	16,094	16,756
6	9	12	17	169	805	194	202
875	1,230	1,662	2,332	23,251	110,743	26,655	27,751
0	0	0	0	1	3	1	1
256	360	486	682	6,801	32,394	7,797	8,118
542	762	1,029	1,443	14,394	68,557	16,501	17,180
4,291	6,032	8,150	11,431	113,987	542,918	130,677	136,050
211	297	401	563	5,614	26,740	6,436	6,701
3,658	5,142	6,948	9,745	97,174	462,837	111,402	115,983
94	132	179	251	2,502	11,915	2,868	2,986
772	1,084	1,465	2,055	20,493	97,606	23,493	24,459

2	3	5	6	63	302	73	76
39	55	74	103	1,031	4,910	1,182	1,230
28	39	53	75	744	3,545	853	888
C	0	0	0	0	0	0	0
276	388	524	735	7,327	34,896	8,399	8,745
1	2	2	3	29	136	33	34
525	738	998	1,399	13,954	66,462	15,997	16,655
2	2	3	4	43	204	49	51
28	40	54	75	749	3,565	858	893
2,890	4,062	5,489	7,699	76,768	365,646	88,009	91,627
34,982	49,167	66,436	93,182	929,168	4,425,600	######	######
34,353	48,284	65,241	91,507	912,464	4,346,042	######	######
1,004	1,411	1,906	2,674	26,663	126,994	30,567	31,824
413	580	784	1,100	10,965	52,224	12,570	13,087
2,577	3,622	4,894	6,864	68,444	325,995	78,465	81,691
5,019	7,054	9,531	13,368	133,302	634,914	152,820	159,104
1,192	1,675	2,264	3,175	31,659	150,791	36,294	37,787
30	43	57	81	803	3,827	921	959
1,403	1,973	2,665	3,738	37,277	177,551	42,736	44,493
32	46	62	87	863	4,109	989	1,030
2,287	3,214	4,343	6,091	60,735	289,279	69,628	72,491
23	33	45	62	623	2,968	714	744
110	154	209	293	2,919	13,905	3,347	3,484
93	131	176	247	2,467	11,752	2,829	2,945
2,666	3,746	5,062	7,100	70,800	337,218	81,166	84,504
2,000	1	1	1	11	51	12	13
4,087	5,744	7,762	10,887	108,559	517,064	124,454	129,572
.,	7	10	14	141	672	162	168
125	175	237	332	3,308	15,755	3,792	3,948
101	141	191	268	2,673	12,733	3,065	3,191
1,057	1,485	2,007	2,815	28,070	133,697	32,180	33,503
26	37	49	69	690	3,287	791	824
1,722	2,420	3,270	4,586	45,729	217,806	52,425	54,580
21	30	41	57	571	2,720	655	682
245	345	466	653	6,512	31,019	7,466	7,773
11	15	20	28	282	1,341	323	336
146	205	277	388	3,868	18,421	4,434	4,616
181	254	343	481	4,799	22,859	5,502	5,728
13	18	24	34	342	1,630	392	408
115	162	219	307	3,061	14,577	3,509	3,653
1,940	2,727	3,684	5,168	51,531	245,439	59,076	61,505
10	14	20	27	274	1,304	314	327
2,161	3,037	4,104	5,756	57,399	273,388	65,803	68,508
2,101	9	12	17	168	798	192	200
279	392	529	742	7,401	35,249	8,484	8,833
17	24	32	45	451	2,149	517	539
440	619	836	1,173	11,699	55,721	13,412	13,963
479	674	911	1,277	12,735	60,659	14,600	15,200
32	45	61	86	855	4,075	981	1,021
	32	43	61	604	2,876	692	721
23							20,956
661 14	929 20	1,255 27	1,761 37	17,558 371	83,626 1,769	20,128 426	443

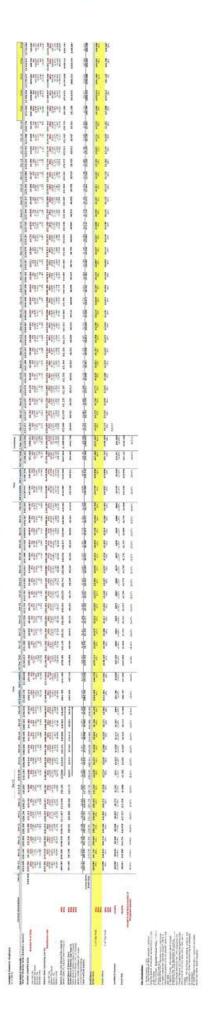
41,441	39,805	165,375	34,721	3,482	2,483	1,837	1,307
166	159	662	139	14	10	7	5
3,114	2,991	12,428	2,609	262	187	138	98
22,899	21,994	91,378	19,185	1,924	1,372	1,015	722
436,914	419,659	1,743,535	366,060	36,711	26,173	19,370	13,782
400,448	384,633	1,598,014	335,508	33,647	23,989	17,754	12,631
36,601	35,156	146,061	30,666	3,075	2,193	1,623	1,155
1,446	1,389	5,769	1,211	121	87	64	46
41,530	39,890	165,728	34,795	3,489	2,488	1,841	1,310
216	208	862	181	18	13	10	7
56,639	54,402	226,023	47,454	4,759	3,393	2,511	1,787
2,821	2,709	11,256	2,363	237	169	125	89
3,745	3,597	14,944	3,138	315	224	166	118
58,786	56,464	234,590	49,253	4,939	3,522	2,606	1,854
1,099	1,056	4,387	921	92	66	49	35
76,358	73,342	304,712	63,975	6,416	4,574	3,385	2,409
4,207	4,041	16,788	3,525	353	252	187	133
4,697	4,511	18,744	3,935	395	281	208	148
780	749	3,114	654	66	47	35	25
18,712	17,973	74,672	15,678	1,572	1,121	830	590
26	25	102	21	2	2	1	1
54,475	52,323	217,385	45,641	4,577	3,263	2,415	1,718
0	0	0	0	0	0	0	0
2,229	2,141	8,896	1,868	187	134	99	70
2,679	2,574	10,693	2,245	225	161	119	85
44,520	42,762	177,660	37,300	3,741	2,667	1,974	1,404
0	0	0	0	0	0	0	0
75,949	72,949	303,079	63,632	6,381	4,550	3,367	2,396
0	0	0	0	0	0	0	0
2,833	2,722	11,307	2,374	238	170	126	89
2,183	2,097	8,713	1,829	183	131	97	69
85,281	81,913	340,321	71,451	7,166	5,109	3,781	2,690
155	149	618	130	10.024	9	7	5
128,827	123,739	514,093	107,935	10,824	7,717	5,711	4,064
15 061	14 466	771	12 610	1 265	12	9 668	475
15,061	14,466	60,102	12,619	1,265	902		
830 39,791	797	3,311	695	70 3,343	2 204	1 764	1 25
334	38,219 320	158,787 1,331	33,338 279	28	2,384	1,764	1,255 11
72,253	69,400	288,332	60,536	6,071	4,328	3,203	2,279
584	561	2,329	489	49	35	26	
1,021	981	4,075	855	86	61	45	18 32
306	294	1,222	257	26	18	14	10
10,056	9,659	40,129	8,425	845	602	446	317
71	69	285	60	6	4	3	2
13,979	13,427	55,786	11,712	1,175	837	620	441
2,451	2,354	9,779	2,053	206	147	109	77
2,731	2,334	5,115	2,000	200	141	103	//

### Exhibit 2

Contract Assumptions Fight 1 Nativity N	SHARE OF GENERIC 50% (\$ in 000's)									Sep-12	2					-	Total	_	
State   Stat		Contract Assumptions	Feb-12		Apr-12	May-12	Jun-12	Jul-12	Aug-12	8/6-1/6	9/8-9/30	Oct-12	Nov-12	Dec-12	Jan-13	Feb-13	1st 6 months 2	nd 6 months, F	ull Year Tot
Part	Total Escitalopram Sales (Branded + Generic)				\$185,081	17	ı,		\$186,213	\$50,628	\$139,227	\$190,376	\$183,620		9	\$177,435	\$1,177,665	\$1,078,104	\$2,255,769
Substitution rate   Subs	Branded LEXAPRO Sales  Branded % of Total  Branded Tax Share Branded Tax Share Branded Units		\$189,739	\$96,053 50% 15,987 5,66% 904 35,078	1,72% 1,72% 1,72% 10,257	\$22,893 12% 15,343 1,40% 215 8,360	\$21,333 11% 15,623 1,28% 200 7,791	\$20,352 11% 15,828 1,21% 191 7,433	\$17,369 9% 15,436 1.05% 163 6,343	\$4,228 8% 6,212 0.94% 2,287	\$11,626 \$93.77 0.94% 88 3,431	\$14,107 7% 15,756 0.84% 132 5,152	\$11,889 6% 15,185 0.73% 111 4,342	\$10,604 5% 16,182 0,61% 99 3,873	\$10,179 5% 15,790 0.56% 88 3,458	\$8,658 5% 14,614 0.51% 75 2,941	\$210,312 18% 99,818 2.00% 1,996 77,549	\$67,063 696 86,895 0.6896 594 23,196	\$277,375 12% 186,663 1,39% 2,590 100,744
Particle	Generic Sales (Assuming Lox PX) Substitution rate Ceneric TRX Share Generic TRX Share Generic Units			\$96,053 \$0% 15,087 5,66% 904 35,078	\$156,996 85% 15,390 9,59% 1,477 57,335		\$166,841 15,623 15,623 10,03% 1,567 60,930	\$170,446 \$9% 15,628 10.10% 1,599 62,245	\$168,844 91% 15,436 10,26% 1,583 61,662	\$46,400 \$295 6,212 10.37% 644 25,141	9,27,601 9,217 10,37% 966 37,712	\$176,269 9346 15,756 10,47% 1,650 64,478	\$171,732 94% 15,185 10,58% 1,605 62,818	\$185,226 95% 16,182 10,70% 1,731 67,754	95% 15,7% 10,75% 1,697 66,487	95% 14,614 10.80% 1,578 61,847	\$967,353 82% 99,818 9.31% 9,294 361,471	\$1,011,041 94% 86,845 10.63% 9,229 361,096	\$1,978,394 88% 186,663 9,92% 18,522 7,22,566
Second Communic (Mark)   State   Second Se	Generic Sales (Px Discount Mar-Sept 8) Generic Sales (Px Discount Sept 9 Forward )	96.06		\$57,632	\$94,198				\$101,307	\$27,840	\$12,760	\$17,627	\$17,173	\$18,523	\$18,144	\$16,878	\$580,412	\$101,104	\$681,516
(Underdeck AP), Forest (Undeck AP), Forest (Unde	Mylan Share of Generic (Mar) Mylan Share of Generic (Apr-Sept 8) Mylan Share of Generic (Sept 9 Forward)	80% 60% 50%		\$46,106	\$56,519	\$58,238	\$60,063	\$61,360	\$60,784	\$16,704	\$6,380	\$8,813	\$8,587	\$9,261	\$9,072	\$8,439	\$359,773	\$50,552	\$410,326
\$\$\current{\cur	neric COGS (Lundbeck API, Forest anufacturing/packaging) otal Profit on Generic			\$1,673	\$2,050 \$54,468	\$2,113	\$2,179	\$2,226	\$2,205	\$899	\$1,124	\$1,921	\$1,872	\$2,019	\$7,091	\$2,843	\$346,429	\$39,761	\$24,105
% of Total Profit 40% 40% 40% 40% 40% 40% 40% 40% 40% 40%	Profit Share Mylan share % of Total Profit			\$26,660	\$32,681	\$33,675 60%	\$34,730	\$35,481	\$35,147	\$9,483 60%	\$3,154	\$4,135	\$4,029	\$4,345 50%	\$4,254	\$3,987	\$207,857	\$23,875	\$231,732
	Forest share % of Total Profit			\$17,773	\$21,787	\$22,450	\$23,154	\$23,654	\$23,432	\$6,322 40%	\$2,102 40%	\$2,757	\$2,686	\$2,897	\$2,836 40%	\$2,638	\$138,572 40%	\$15,917 40%	\$154,488

### Assumptions:

1. Market Growth - 1% to 1. Market Growth - 1% to 10da 155(datoperm have transmiss flat at 11.31%) following generic introduction remains flat at 11.31% of Still Market 2012 and 2013 and 2014 and 2013 and 2013 and 2014 and 2013 and 2013 and 2014 and 2013 and 2013



# EXHIBIT 278

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1		3
IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE	1	APPEARANCES:
SANGAN CANAGE USAGE CANAGAN ASSES A SANGAN S	2	KIRKLAND & ELLIS LLP
FOREST LABORATORIES INC., ET AL., )	3	Attorneys for Plaintiff Forest Laboratories
Plaintiffs,	4	Inc. and the Deponent
)	5	601 Lexington Avenue
vs. )C.A. No. )08-21-GMS-LPS	6	New York, New York 10022-4611
COBALT LABORATORIES INC., ET AL.,)	7	BY: GERALD J. FLATTMANN, JR., ESQ.
Committee of the confidence and appropriate the confidence of the	8	(212) 446-4720 gflattmann@kirkland.com
Defendants. )	9	-and-
	10	BY: GREGORY A. MORRIS, ESQ.
VIDEOTAPED DEPOSITION OF	11	(212) 446-4856 gmorris@kirkland.com
WALTER WOLFGANG FLEISCHHACKER, M.D.	12	Tentes E III
New York, New York Wednesday, September 9, 2009	13	JONES DAY
# 10 # 10 # 10 # 10 # 10 # 10 # 10 # 10	14	Attorneys for Plaintiff Merz and the Deponent
	15	222 East 41st Street
Reported by:	16	New York, New York 10017-6702
Jennifer Ocampo-Guzman	17	BY: F. DOMINIC CERRITO, ESQ.
JOB NO. 303128	18	(212) 326-3939 fdcerrito@jonesday.com
	19	DALCOCTY MODULE MAZZZOOU CHARK LLD
	20	RAKOCZY MOLINO MAZZOCHI SIWIK LLP
	21	Attorneys for Defendant Cobalt
	22	6 West Hubbard Street, Suite 500
	23	Chicago, Illinois 60610
	24	BY: NEIL A. BENCHELL, ESQ. (312) 222-6346 nbenchell@rmmslegal.com
<b>2</b> 0	12.5	
2		4
1	1	
2		APPEARANCES (Continued):
3	3	
4	4	BUDD LARNER, PC
5	5	Attorneys for Defendant Dr. Reddy's
6	6	Laboratories
7	7	150 JFK Parkway
8 September 9, 2009	8	Short Hills, New Jersey 07078
9 <b>8:21 a.m.</b>	9	BY: LOUIS WEINSTEIN, ESQ.
Appropriate to a property and a management of the property of	10	(973) 379-4800 lweinstein@buddlarner.com
11 Videotaped Deposition of WALTER 12 WOLFGANG FLEISCHHACKER, M.D., held at the	11	SCHIEF HARRIN I I D
	12	SCHIFF HARDIN LLP
offices of Kirkland & Ellis, LLP, 601 Lexington Avenue, New York, New York,	13 14	Attorneys for Defendant Lupin Pharmaceuticals
pursuant to subpoena, before Jennifer	15	1666 K Street, NW, Suite 300 Washington, DC 20006
16 Ocampo-Guzman, a Notary Public of the State	16	BY: D. CHRISTOPHER OHLY, ESQ.
of New York.	17	(202) 778-6458 dcohly@schiffhardin.com
		(LUL) 110-0400 GCOIN (WSCIIIIII GIGIII.COIII
18		
18	18	CON 10 PRINTED
19	18 19	WILLKIE FARR & GALLAGHER, LLP
19 20	18 19 20	WILLKIE FARR & GALLAGHER, LLP Attorneys for Defendant Teva Pharmaceuticals
19 20 21	18 19 20 21	WILLKIE FARR & GALLAGHER, LLP Attorneys for Defendant Teva Pharmaceuticals 787 Seventh Avenue
19 20 21 22	18 19 20	WILLKIE FARR & GALLAGHER, LLP Attorneys for Defendant Teva Pharmaceuticals 787 Seventh Avenue New York, New York 10019-6099
19 20 21	18 19 20 21 22	WILLKIE FARR & GALLAGHER, LLP Attorneys for Defendant Teva Pharmaceuticals 787 Seventh Avenue



Toll Free: 800.944.9454 Facsimile: 212.557.5972

Suite 4715 One Penn Plaza New York, NY 10119 www.esquiresolutions.com

	5		7
1		1	(Exhibit Fleischhacker-1, Document
2	APPEARANCES (Continued):	2	entitled, "Memantine in the Treatment of Senile
	X	3	Dementia of the Alzheimer Type," marked for
S	LATHAM & WATKINS, LLP	4	identification, this date.)
į.	Attorneys for Defendant Orchid	5	(Exhibit Fleischhacker-2, Article,
	Pharmaceuticals	6	[German language], marked for identification, this
8	885 Third Avenue	7	date.)
	New York, New York 10022-4834	8	(Demonstrative Exhibit Fleischhacker-3,
	BY: TERRENCE J. CONNOLLY, ESQ.	9	Poster, Fleischhacker Exhibit 1 at page 88, "Drug
	(212) 906-1853 terrence.connolly@lw.com	10	administration," marked for identification, this
	=	11	date.)
	VIA TELEPHONE:	12	(Demonstrative Exhibit Fleischhacker-4,
	WILSON SONSINI GOODRICH & ROSATI, LLP	13	Poster, Fleischhacker Exhibit 1 at page 89, marked
	Attorneys for Mylan Pharmaceuticals and	14	for identification, this date.)
	GenPharm Pharmaceuticals	15	(Demonstrative Exhibit Fleischhacker-5,
	12235 El Camino Real	16	Poster, Fleischhacker Exhibit 1 at page 89,
	San Diego, California 92130	17	"Discussion," marked for identification, this
	BY: LORI WESTIN, ESQ.	18	date.)
	(858) 350-2300 lwestin@wsgr.com	19	(Demonstrative Exhibit Fleischhacker-6,
		20	Poster, Fleischhacker Exhibit 1 at page 89,
	ALSO PRESENT:	21	"Discussion," marked for identification, this
	JUAN TORRES, Videographer	22	date.)
	CHARLES RYAN, J.D., Ph.D. (Forest Research)	23	(Demonstrative Exhibit Fleischhacker-7,
	PATRICK M. JOCHUM (Merz)	24	Poster, Fleischhacker Exhibit 1 at page 92,
Š	8 2	25	"Conclusions," marked for identification, this
	6		8
E)	EXHIBITS	1	date.)
	FLEISCHHACKER EXHIBITS FOR I.D.	2	THE VIDEOGRAPHER: This is tape
	Exhibit Fleischhacker-1, Document Entitled, "Memantine in the Treatment	3	number 1 of the videotaped deposition of Dr. W.
	of Senile Dementia of the Alzheimer	4	Wolfgang Fleischhacker, in the matter Forest
	Type"6	5	Laboratories Inc., et al, versus Cobalt
	Exhibit Fleischhacker-2, Article,	6	Laboratories Inc., et al., in the United States
	[German language]6 Demonstrative Exhibit Fleischhacker-3,	7	District Court, for the District of Delaware.
	Poster, Fleischhacker Exhibit 1 at page 88,	8	This deposition is being held at
	"Drug administration"6  Demonstrative Exhibit Fleischhacker-4,	9	Kirkland & Ellis, LLP, 601 Lexington Avenue,
	Poster, Fleischhacker Exhibit 1 at	10	New York, New York, on September 9, 2009, at
	Page 896  Demonstrative Exhibit Fleischhacker-5.	11	approximately 8:21 a m
	Demonstrative Exhibit Fleischhacker-5, Poster, Fleischhacker Exhibit 1 at page 89,	11 12	approximately 8:21 a.m.  My name is the Juan Torres, and I am
	Demonstrative Exhibit Fleischhacker-5, Poster, Fleischhacker Exhibit 1 at page 89, "Discussion"6	12	My name is the Juan Torres, and I am
	Demonstrative Exhibit Fleischhacker-5, Poster, Fleischhacker Exhibit 1 at page 89, "Discussion"	12 13	My name is the Juan Torres, and I am the legal video specialist.
	Demonstrative Exhibit Fleischhacker-5, Poster, Fleischhacker Exhibit 1 at page 89, "Discussion"	12 13 14	My name is the Juan Torres, and I am the legal video specialist. Will counsel please introduce
	Demonstrative Exhibit Fleischhacker-5, Poster, Fleischhacker Exhibit 1 at page 89, "Discussion"	12 13 14 15	My name is the Juan Torres, and I am the legal video specialist.  Will counsel please introduce themselves, beginning with the party noticing this
	Demonstrative Exhibit Fleischhacker-5, Poster, Fleischhacker Exhibit 1 at page 89, "Discussion"	12 13 14 15 16	My name is the Juan Torres, and I am the legal video specialist. Will counsel please introduce themselves, beginning with the party noticing this proceeding.
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	9		11
1	DR. RYAN: Charles Ryan with Forest	1	of the department of psychiatry and psychotherapy.
2	Laboratories.	2	Q. And what are your principal duties and
3	DR. JOCHUM: Patrick Jochum with Merz	3	responsibilities in that role?
4	Pharmaceuticals.	4	<ol> <li>I have clinical responsibilities in</li> </ol>
5	MR. WEINSTEIN: Louis Weinstein, with	5	patient care. I have responsibilities with regard
6	Budd Larner PC, on behalf of Dr. Reddy's	6	to teaching and research.
7	laboratories.	7	Q. How long have you been working at
8	MR. OHLY: Chris Ohly, Schiff Hardin,	8	Innsbruck University?
9	for Lupin.	9	A. Thirty years.
LO	MR. BENCHELL: Neil Benchell, with	10	Q. Could you please describe your research
11	Rakoczy Molino Mazzochi Siwik, for Cobalt.	11	at Innsbruck University.
12	MR. CHANG: Eugene Chang, Willkie Farr	12	A. My main focus in research is
13	& Gallagher, for Teva.	13	psychopharmacology.
4	MR. CONNOLLY: Terrence Connolly,	14	Q. What is psychopharmacology?
.5	Latham & Watkins, for Orchid Pharmaceuticals.	15	A. Psychopharmacology is the science and
6	MR. FLATTMANN: And may I ask if anyone	16	also the clinical practice of administering drugs
.7	is on the telephone line right now?	17	to treat psychiatric disorders.
1.8	MR. BENCHELL: Actually, I am just	18	<ul> <li>Q. And you mentioned that you teach as</li> </ul>
19	getting an e-mail now. Apparently there is, and	19	well.
0.5	apparently the phone is muted, so.	20	What do you teach?
21	MR. FLATTMANN: Oh, let's fix that.	21	<ul> <li>A. I teach psychiatry and</li> </ul>
22	Let's unmute the phone.	22	psychopharmacology.
23	Is there anyone joining us on the	23	Q. And what type of students do you teach?
24	phone? We're doing attorney introductions, for	24	<ul> <li>A. Medical students and also students who</li> </ul>
25	the record.	25	go for psychology Ph.D. degrees.
	10		12
1	MS. WESTIN: Good morning, this is Lori	1	Q. Let me ask you a few questions about
2	Westin, for Mylan and GenPharm.	2	your educational background.
3	MR. OHLY: From California?	3	Do you hold any degrees?
4	MS. WESTIN: From California.	4	A. An MD.
5	MR. FLATTMANN: Okay.	5	Q. An MD. So you have a medical degree?
6	THE VIDEOGRAPHER: Will the court	6	<ol> <li>I have a medical degree.</li> </ol>
7	reporter please swear in the witness.	7	Q. Do you have any other degrees?
8	WALTER WOLFGANG	8	A. Nope.
9	FLEISCHHACKER, M.D., called as a	9	Q. And where did you receive your medical
10	witness, having been duly sworn by a Notary	10	degree?
11	Public, was examined and testified as follows:	11	<ol> <li>At the University of Innsbruck.</li> </ol>
12	EXAMINATION BY	12	Q. Do you hold any membership in any
13	MR. FLATTMANN:	13	professional associations or organizations?
14	Q. Good morning, Dr. Fleischhacker.	14	A. Yes. I'm a member of the European
15	A. Good morning.	15	College of Neuropsychopharmacology, of the
16	Q. Would you please state your full name	16	Schizophrenia Research Society, of the Austrian
17	for the record?	17	Society of Psychiatry and psychotherapy. I'm a
18	<ul> <li>A. Walter Wolfgang Fleischhacker.</li> </ul>	18	foreign correspondent fellow of the American
19	Q. What do you do for a living?	19	College of Neuropsychopharmacology. I am a member
20	A. I'm a psychiatrist.	20	of the International College of
21	O Whore do you work?	2.1	Mauronsychopharmacology

21

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23

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Neuropsychopharmacology.

professional publications?

Q. Are you on the editorial staff of any

A. Yes. I'm on the editorial board of the

Journal of Clinical Psychopharmacology, of



Innsbruck.

Q. Where do you work?

A. I work at the Medical University of

My position there is managing director

Q. What is your position there?

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23 24

waı	ter wolfgang Fleischnacker, M.D.	2	September 9, 2009
	169		171
1	A. Actually, I'm sorry, I may have mixed	1	A. The evidence that was available at that
2	that up. It's the other way around.	2	time.
3	So one of the tests measures group	3	Q. Do you recall what evidence that was?
4	differences, the other test measures the long-term	4	A. Not in detail, but clinical trials that
5	course of the disorder. And it's exactly the	5	were published.
6	other way around than I had explained to you. I	6	Q. What kinds of clinical trials were
7	apologize.	7	these?
8	Q. So the Wilcoxon wilcox is the long-term	8	A. They were randomized, controlled
9	statistical	9	clinical trials.
10	A. Is the long term, and the U-Test is the	10	Q. Do you earlier you mentioned that
11	one that measures the group differences.	11	the understanding of the mechanism of action of
12	Q. Have you used these statistical	12	memantine has changed over time.
13	analyses in any of your other studies?	13	Do you recall that?
14	A. Before or after?	14	A. Yes, I recall that.
15	Q. Before or after.	15	<ul> <li>Q. When you say that, the actual mechanism</li> </ul>
16	MR. FLATTMANN: Objection, vague as to	16	of action itself hasn't changed, it's just our
17	which analyses.	17	understanding of it that's changed, right?
18	Q. All right. Let's take them one at a	18	A. Correct.
19	time.	19	<ul> <li>Q. So every time you give a drug to</li> </ul>
20	Have you used the Wilcoxon-Wilcox	20	someone, it operates the same way, regardless of
21	statistical analysis in any of your other studies?	21	whether people have discovered that interaction?
22	A. After we did this one?	22	MR. FLATTMANN: I would like to hear
23	Q. Yes.	23	the question one more time, please.
24	A. Yes.	24	I need to hear the entire question.
25	Q. Did you use it in any of the ones	25	(A portion of the record was read.)
	170		172
1	before this study, the memantine study?	1	MR. FLATTMANN: I object to the
2	A. You know, I'm not sure.	2	question as lacking in foundation and vague and
3	Q. How about the U-Test, have you used the	3	ambiguous. Also calling for an expert opinion.
4	U-Test statistical analysis in any studies before	4	A. Drugs given to different people
5	or after the memantine study?	5	generally also work in different ways in different
6	A. After, yes, certainly. Before, I'm not	6	people. As a general principle, that probably is
7	sure.	7	transferable from one person to the other; but in
8	Q. Do you currently use memantine to treat	8	subtle detail there may be huge intraindividual or
9	Alzheimer's patients?	9	interindividual differences.
10	A. Yes.	10	Q. But for any particular person, every
11	Q. Do you believe that memantine works to	11	time you give that drug to them, it operates the
12	treat Alzheimer's patients today?	12	same way, regardless of whether we understand the
13	MR. OHLY: Objection. I object to that	13	mechanism of action, right?
14	question.	14	MR. FLATTMANN: Objection, vague and
15	MR. CERRITO: You can answer.	15	ambiguous, lacks foundation, calls for an expert
4 6		3.5	

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Go ahead. A. I don't think it's a matter of belief.

There is scientific evidence that it helps people with Alzheimer's disease.

Q. And when did you start prescribing memantine for Alzheimer's patients?

A. I started prescribing that shortly after it was licensed in Austria.

Q. What was it that convinced you to start prescribing memantine for Alzheimer's patients? opinion and is an incomplete hypothetical.

A. I don't think it can be stated in that way. As I stated before, there are interindividual differences in how people react to drugs.

Q. Let me ask the question a slightly different way, then.

Do you believe that, according to what you know sitting here today, that memantine is an NMDA antagonist?



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# EXHIBIT 279

	Page 1
1	** HIGHLY CONFIDENTIAL **
2	UNITED STATES DISTRICT COURT
3	SOUTHERN DISTRICT OF NEW YORK
4	Civil Action No. 1:15-cv-07488-CM
5	x
6	
	IN RE NAMENDA DIRECT PURCHASER
7	ANTITRUST LITIGATION
8	
9	x
	August 29, 2017
10	8:49 a.m.
11	
12	
13	Videotaped Deposition of FOREST
L 4	LABORATORIES, LLC; ACTAVIS, PLC; FOREST
15	LABORATORIES, INC.; and FOREST LABORATORIES
1 6	HOLDINGS LTD., by MARK DEVLIN, taken by
17	Plaintiffs, pursuant to Rule 30(b)(6)
18	Notice, held at the offices of Garwin
19	Gerstein & Fisher LLP, 88 Pine Street, New
2 0	York, New York, before Todd DeSimone, a
21	Registered Professional Reporter and Notary
2 2	Public of the State of New York.
23	
2 4	
2 5	

Page 43 Page 44 MARK DEVLIN ARK DEVLIN 1 1 2 What is your understanding of that 2 e-mail, did you talk to any of the accounts for which you had 3 3 language? 4 Α I don't know what responsibility, concerning the decision 5 Mr. Samoriski exactly meant with his that Mr. Samoriski writes about here? Y es. I believe I did. 6 statement. I'm asking for your T o whom did you talk in terms of companies, not individuals? ₿ understanding when you read this. ₿ 9 My understanding is that to 9 I believe I personally spoke transition patients to Namenda XR with Express Scripts, silver script 10 10 division of CVS Caremark, Humana. Those 11 requires the physician to make the 11 12 judgment. That's what they want the are three I can recall right now. W hat did you tell Express 13 patient to be on and to write the 13 0 14 prescription for it. 14 Scripts about Forest's decision to 0 And you didn't understand discontinue IR? 15 15 16 that to mean Forest's transition of 16 I think it was a general 17 patients to XR? 17 discussion about Namenda XR and the acceptance of that and that I think I MR. TOTO: Object to form. 18 1.8 asked their opinion regarding the As I said before, my view is possibility of, I guess, the approach we 20 Forest does not transition patients. A 20 21 physician does that. were considering to only sell Namenda XR, 21 the oral solid version. 22 o In the next paragraph, he talks about 22 23 effective communication. Do you see that? 23 Q W hat did ESI say to you Α about that? 25 After you received this 25 A E SI? VERITEXT REPORTING COMPANY VERITEXT REPORTING COMPANY 212-267-6868 www.veritext.com 516-608-2400 212-267-6868 516-608-2400 www.veritext.com

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Page 45

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1
                   M ARK DEVLIN
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                 E xpress Scripts.
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                 T hey specifically thought it
     was a good business decision and said
     that they were happy with Namenda XR from
 5
     their view.
 6
         0
                 W hat about CVS?
 ₿
                 C VS Caremark, I spoke with
     the individuals on their -- for their
10
     silver script plan which is a Medicare
     plan. And they were indifferent, said it
     wouldn't matter to them.
12
13
                W hat about Humana?
14
                 S imilar story. I spoke to
    the Medicare Part D people at Humana.
1.5
     And they also were indifferent, didn't
     have an opinion, one way or another, as
17
     to what their situation would be if we
19
     only sold Namenda XR.
20
         o
                 D id any of these three
21
     companies mention to you that they were
22
     concerned about moving patients to
     generic IR if IR was discontinued?
               M R. TOTO: Object to form.
24
25
                 M ost of the discussions I
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Page 61 1 modeled, were you asking either of the recipients of this e-mail to do the 2 modeling or make sure it was done? 3 I was suggesting that it be done. 6 And did you follow up to see ο. that it was done? I don't recall if I did or I 8 9 did not. 10 Q. You have no recollection after 11 this you made any effort to find out whether it was actually modeled? 12 13 I know we -- I know we modeled the conversion back from Namenda XR to 14 generic IR, but I don't -- I don't -- I 15 didn't follow up specifically or I don't 16 17 recall following up specifically on this 18 suggestion. 19 Q. And do you believe that either of the recipients of your e-mail would be 20 21 doing the modeling or did you expect that 22 they would have someone else do the 23 modeling? 24 I don't know. I don't know who on their team they might have gone to to do

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Page 62 1 the modeling or if they would have done it 2 themselves. 3 Okay. You can put that aside, MR. TOTO: When you get to a point, maybe a good time for a break. MR. SORENSEN: Yeah, one more 8 document? 9 MR. TOTO: Sure. 10 If you need a break, we can Q. 11 12 No. I can do one more. Α. 13 One more document? I can do one more. 14 Α 15 Fair enough. (Devlin Exhibit 7 marked for 16 17 identification.) 18 ο. Sir, what I have marked as 19 Exhibit 7 is Bates numbers FRX-AT-03861621 It is titled Namenda XR Roadmap to Launch 20 21 dated September 13th, 2012. Do you see 22 that, sir? 23 Α. 24 Have you seen this before? It does not look familiar, no. Veritext Legal Solutions

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#### Page 63

- If you turn to Bates page 1623. MR. TOTO: Again, take your time to familiarize yourself with the document.
- Sure. It is just a page that says the word Brand Goals.
  - A T see it

MR. TOTO: I figure you are going to ask something.

MR. SORENSEN: I will.

I just want to orient, take you to it.

And then the next page repeats, Brand Goals, this is Bates page that ends 1624, and under Brand Goals it says "Namenda XR is a significant brand which is expected to produce net sales over \$500 million at peak. Conversion," then it says "30 percent of Rxs" -- that stands for prescriptions, correct?

- Α. Correct.
- -- "from IR in 18 months. Reverse conversion in 3 years post IR LOE," and then it has various numbers and it has a cumulative number of 30 percent.

HIGHLY CONFIDENTIAL Page 64 1 Do vou see that? 2 I do. Now, the conversion number of 30 percent of prescriptions in 18 months, 5 do you understand that at this time that was Forest's, quote, "brand goal," at the MR. TOTO: Objection, the 8 9 document speaks for itself, lacks 10 foundation. 11 Yes, it appears that the 30 12 percent of prescriptions from IR was a 13 brand goal, yes, for conversion. 14 And apart from staring at this 15 work at Forest around this time that that 16 18

on the page, were you familiar just in your was the number that Forest was setting as a goal for conversion at this time from IR to

MR. TOTO: I object to form, lacks foundation.

- If you turn -- look at the next page, Bates number 1625, it says Namenda Franchise Forecast, Net Sales in Millions.

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Page 69 1 in your role at Forest at this time? In 2 other words, if we take the document date 3 on the metadata as October 19th, 2012, why would you have seen this in your role at Forest at that time? I may have been in a meeting 7 where Laura Mastrosimone or someone else 8 from the brand team presented this 9 presentation. 10 Q. Are you saying you may have, or 11 do you recall as you sit here that you 12 actually were? 13 I'm just trying to understand how, you know, how specific your 14 15 recollection is. No, I don't -- I don't recall a 16 17 specific meeting. The document looks familiar to me. 18 19 Q. I see, okay. 20 It may have been presented. I 21 may have been present in a meeting or it 22 may have been sent to me. I don't know. 23 Okay, fair enough. 24 And on the page right after

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	Page 70
1	care. Do you see that?
2	A. Which page?
3	Q. This is right after the 30
4	percent, it is Bates page 6056.
5	A. Okay, yeah.
6	Q. And that long-term care is
7	often abbreviated in Forest documents as
8	LTC, correct?
9	A. Correct.
10	Q. So, for example, on Bates page
11	6058, you see the abbreviation LTC
12	Physicians; do you see that?
13	A. I do.
14	Q. And that refers to long-term
15	care physicians, correct?
16	A. Yes.
17	Q. And a significant amount of the
18	patient population using Namenda, since
19	it's an Alzheimer's treatment, live in
20	long-term care facilities; is that correct?
21	A. I don't know how you would
22	define significant percentage, but, yeah,
23	there was a fair amount of use of Namenda,
2 4	because it is an Alzheimer's medication, in
25	long-term care.
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that, there is a reference to long-term

	Page 71
1	Q. And Forest endeavored to study
2	what percentage of the Namenda patient
3	population resided in long-term care
4	facilities, correct?
5	A. Yes.
6	Q. If you turn to the Bates page
7	that ends 6061 of this document, it is
8	entitled Master Timeline. Do you see that?
9	A. I do.
10	Q. This kind of timeline giving
11	different events, is that something that
12	you're familiar with?
13	A. Yes.
14	Q. And MCO training, what does MCO
15	stand for?
16	A. Managed care organization.
17	Q. Okay, you can put that document
18	aside, sir.
19	(Devlin Exhibit 9 marked for
20	identification.)
21	Q. Sir, what I have marked as
22	Exhibit 9 bears Bates number
23	FRX-AT-03716706.
2 4	It is an e-mail dated March
25	11th, 2013 from a Lei Meng to Elizabeth

	Page 72
1	Fung, with attachment. Do you see that?
2	A. I do.
3	Q. And who is Lei Meng?
4	A. Lei Meng was a Forest
5	Laboratories employee in our Business
6	Development and Commercial Assessment
7	Group.
8	Q. Is she still employed by Forest
9	or some corporate successor?
10	A. Yes.
11	Q. Was she involved in developing
12	forecasts for Namenda IR/XR?
13	A. Yes.
14	Q. So will you now add her to your
15	list that you gave earlier?
16	A. Yes, I would.
17	Q. And how about Elizabeth Fung,
18	who is she?
19	A. She was another person on the
2 0	Brand Marketing team.
21	Q. Would Ms. Fung also have been
22	involved in creating forecasts?
2 3	A. I don't know.
2 4	Q. But Lei Meng was?
2 5	A. Yes.

Page 93 Other than looking at this document, did you understand that these were among Forest's internal goals in trying to understand the expected conversion rate from branded IR to branded XR? MR. TOTO: I object to form. That what was Forest's goals? That what you see in front of you were among Forest's goal in doing analogue analysis? MR. TOTO: I object to form. I'll start again. ο. Did you understand that Forest was trying to identify analogues, the most appropriate analogues, get IMS data for

Yes, that's my understanding.

those analogues, to project, estimate, the

expected conversion of branded IR to XR?

Okay, fair enough.

22 And when it says in the third 23 bullet "factor Namenda conversion for high Namenda share of LTC (44 percent), " other than looking at this document, are you

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Page 94 1 aware of the Namenda business that went to patients in long-term care? 2 3 Was it approximately 44 percent at this time? I thought it was lower. 6 Α. Okay. Do you have some reason to dispute the 44 percent number? 8 9 MR. TOTO: I object to your characterization on 44 percent number. 10 11 MR. SORENSEN: Okay. 12 If you look at the next page, 13 page 7, second bullet, under Methodology, "analogues business breakdown is at least 14 15 somewhat similar to Namenda's percent of TRXs" -- that stands for total 16 17 prescriptions? Do you see TRX? 18 Α. Yes. 19 ο. Does that stand for total 20 prescriptions? 21 22 -- "in long-term care (44 Q. 23 percent)." 24 Do vou see that? 25 Α Yes.

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#### Do you have some basis to dispute that that's an accurate number at this time?

For percentage of prescription, no, I have no basis to dispute it. We looked at prescriptions or volume. Depending upon what you look at, those percentages could be different.

And as far as you know, or -let me start again.

If you go back to the e-mail

from Julie Zaidler and the attachment, as you understand it, she sent this document in the course of her business and employment at Forest at the time, correct?

I don't know who Julie Zaidler From, you know, where it says from Julie Zaidler, it doesn't say, in parentheses, an FRX e-mail, so I don't really know who she is.

But the other individuals who are receiving this document are all Forest employees, correct?

> Ά Correct.

At the time?

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	Page 96
1	A. At the time, correct.
2	Q. And if you would look back at
3	page 5, it says "Questions? Contact: Julie
4	Zaidler," and there is an extension. Does
5	that look like a Forest extension?
6	MR. TOTO: I object to form.
7	A. I don't know.
8	Q. You don't know?
9	A. I don't know.
10	Q. Okay.
11	I may have asked this, so I
12	apologize, but the first line of the e-mail
13	is "Attached are the Namenda XR analogues
14	that you requested."
15	This is written to Maria
16	Theodore. Do you see that?
17	A. Yes.
18	Q. Other than looking at this
19	e-mail, do you have any knowledge that
20	Maria Theodore, a Forest employee at this
21	time, was asking for data on different or
22	newer analogues?
23	A. No, I don't have any knowledge.
2 4	Q. You can put that aside, sir.
25	(Devlin Exhibit 11 marked for

Page 105 1 19, it says 30 percent. 2 If you flip over to the next 3 page and you keep going on line 64, the numbers start dropping. Do you see that? 29 percent, 28 percent, and so forth. This is in black and white. Do you see that? 7 On the page after this --After the yellow. 8 9 -- column 18? Yes, yes. Instead of month 18, 10 ο. 11 month 19 -- on the page that you were 12 looking at with vellow, month 18 says 30 13 percent, month 19 says 30 percent. Do you see that? 14 15 Yes. All right. 16 Q. 17 Now, when you turn the page, 18 now this is all black and white, starting 19 with month 21 and 22 and so forth, that same line, 64, starts at 29 percent, and as 20 21 you move from left to right, it starts to 22 drop. Do you see that? 23 Α. 24 You can put that document aside, sir.

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Page 106 1 MR. TOTO: I move to strike all 2 testimony related to Exhibit 11 based on 3 the fact that the witness testified he cannot read portions of it because the font was too small. 6 You can put that aside, sir. 7 (Devlin Exhibit 12 marked for identification.) 8 9 Sir, what I have marked as Exhibit 12 bears Bates number 10 FRX-AT-01775302. It is titled Namenda IR 11 12 to XR Conversion Project. Working Draft. 13 June 2013. Do you see that, sir? 14 Α ob T 15 Have you seen this document before? 16 17 Parts of it look familiar. 18 ο. So do you believe you've seen 19 the entire document or you've seen portions of this in other documents? 20 21 I don't know. 22 So if you turn to the third 23 page of the document, Bates number ending 5304, it is titled Three Potential Scenarios for Namenda IR Commercial

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Page 107 1 Availability Post XR Launch are Being Considered. Do you see that? 2 3 Α. I do. 4 And underneath that, it says 5 Conventional, Withdrawal, and Limited Distribution. Do you see that? 7 Yes 8 ο. Other than looking at this 9 document, are these terms familiar to you, 10 that is, the terms Conventional, Withdrawal 11 and Limited Distribution, as it relates to 12 Namenda? 13 14 So for Conventional, it says "both Namenda IR and Namenda XR marketed, 15 'soft switch.'" 16 Do you see that? 18 19 Other than looking at this document are you familiar with the term 20 21 "soft switch"? 22 23 And what does it mean to you? 24 A It is a term that is just referring to traditional sales and

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Page 108 1 marketing effort to convince a physician to prescribe one product over another. 2 3 But as indicated in this document, it would also mean that both 5 branded IR and XR are being sold at the same time, correct? 7 8 Now, we go to Withdrawal, 9 underneath that, it says "Namenda withdrawn 10 from the market, 'hard switch.'" Do you 11 see that? 12 Α 13 Is the term "hard switch" 14 something you're familiar with? 15 Α. Yes. 16 Ω And what do you understand it 17 to mean? 18 A Is that both of those products 19 would not be widely available. So that under the Withdrawal 20 21 scenario, once Namenda XR was launched, IR, branded IR would be withdrawn, correct? 22 MR. TOTO: I object to form, 24 lacks foundation. Correct.

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And then to the right of that, we have Limited Distribution, with a description underneath it.

Other than the description that you see in front of you, do you have any other understanding of what Limited Distribution refers to?

MR. TOTO: I object to form.

- What was the question, again?
- In other words, under Limited Distribution, it says -- it has two bullets. Do you see those bullets?
  - T do
- Now, other than what you see in front of you, do you have any other understanding of what the term Limited Distribution means in reference to Namenda? MR. TOTO: I object to form,
- 19 lacks foundation.
- 20 Ά
- 21 What other meaning do you 22 understand it to have?
- 23 Well, insurance companies
- oftentimes have limited retail distribution networks, and oftentimes limited

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Page 110 1 distribution refers to that as well. 2 Q. Well, in this time period of 3 June 2013, I gather Forest was considering a limited distribution option for Namenda IR: is that correct? Α. Yes. 7 And what did you -- I'm sorry, were you finished? 8 9 Yes, I was finished. And what did you understand 10 11 Forest was considering under the rubric of 12 limited distribution for IR? 13 We were considering having Namenda IR be available through a specialty 14 15 pharmacy or mail order pharmacy operation. And is that ultimately 16 17 something that Forest did? 18 Α. We did not. 19 0 And the two bullets under Limited Distribution on this page, do those 20 21 comport with your understanding of part of 22 what Limited Distribution meant? 23 Yes.

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that says Through FY 2014. FY refers to

Now, below that there is a box

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fiscal year, correct?

- What is Forest's fiscal year, or what was it at this time? Was it just the calendar year or was it some other period?
- I'm not sure for this time period of June 2013. At one point our fiscal year definition changed in the transition from Forest to Actavis.
- And when was that transition, again?
- I think that was -- I think that acquisition closed in July of '14, but I'm not sure when we moved to the fiscal year change from one period to a calendar year. It was at one point April to March was a fiscal year and then it moved to calendar year.
  - Is it currently calendar year?
  - It is currently calendar year.
  - You don't know when that change
- I'm not sure. I don't know the 24 A exact date, no.

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- The next bullet says "Decision: Withdrawal or Limited Distribution or Conventional option to be based on degree of success in converting Namenda IR to Namenda XR."
  - Do you see that?
  - ob T
- Does that mean that the decision of which to choose would be the one that has the highest degree of success in converting IR to XR?
- I think it means the decision Α would be based on how Namenda XR was doing in the market at the time.
- Q. All right, you can put that document aside, sir
- (Devlin Exhibit 13 marked for identification )
- So this document which I have marked as Devlin Exhibit 13 bears Bates number FRX-AT-01593279.
- The front of it is an e-mail chain, at the very top is an e-mail from William Meury to a number of individuals, including you, dated August 21, 2013.

Page 189 1 discontinuation of IR is going to make the conversion happen, as he says, "without any 2 effort on MHA's part," correct? 3 Yeah, that's what he's saying. 5 And then on the next page, that is Bates page 7889 at the top, he says, at least as of the date of this e-mail, "The IR/XR conversion of MHA, Forest's largest 8 9 LTC customer collectively, is a pathetic 6 percent and the independent LTC pharmacies 10 11 have had every incentive to switch to XR, 12 including a rebate since launch. The 13 conversion rate is half the national average and half the retail conversion 14 15 rate, and we know retail is doing nothing to switch." 16 17 Do you see that? And it continues. 18 19 Ά 20 Now, your response to him at 21 the top of Bates page 7888 is "As I said in 22 my message, we will discuss on Tuesday, so 23 No Need for further e-mails on this subject please."

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Do you see that?

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Page 190 1 ob T 2 And then you have underlined ο. 3 and capitalized "No Need." Do you see 5 I do. 6 Is that because you didn't want an e-mail record created about this 8 subject? 9 MR. TOTO: Objection, lacks 10 11 foundation, argumentative. 12 It's a question. Go ahead. 13 The answer is no. MR. TOTO: It's an 14 15 objectionable question. 16 So why did you capitalize and 17 underscore "No Need"? 18 Because I was frustrated with 19 Don Robertson's response, and he didn't fully understand what was going on with 20 21 MHA, that customer, and the reason the 22 conversion was lower there was because they 23 were not doing what we were paying them to

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do, which we subsequently took care of and

conversion accelerated as a result.

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- You can put that aside, sir. (Devlin Exhibit 24 marked for identification.)
- Sir, what I have marked as Exhibit 24 bears Bates number FRX-AT-016 -let me start again -- FRX-AT-01630961.

Do you see that, sir?

- Α. Yes.
- February 14th, 2014.

Meury to you, copied to Jerry Lynch, and below that is an e-mail from you to Mr. Meury, copied to Jerry Lynch.

second page of the document, the e-mail chain starts with an e-mail from Jerry Lynch to Mark -- to you, copied to Mr. Meury. Do you see that?

- Yes. I see it.
- Bates page 0962 with Mr. Lynch, who I believe you identified earlier; is that correct?

It's an e-mail chain dated At the top, it is from William And on the other page, the

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So the e-mail chain starts on

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Page 192 1 "Mark," asking you, "What plans 2 do you think we need to contact Tuesday concerning XR? What's the plan for the RAMs and the NAMs the first part of next 5 week?" And it continues. 6 Do vou see that? Yeah. I'm just reading the 8 rest of that. 9 No problem. Go ahead. 10 (Witness perusing document.) 11 12 And your response on Bates page 13 0961 is "I spoke with Optum last week." What is Optum? 14 15 Optum is the pharmacy benefit management division of United Healthcare. 16 "Will send Mike Anderson the 18 press release and call him next week." 19 Who is Mike Anderson? He is a vice president at 20 21 Optum, or he was at the time. "Will do the same" -- "Will do 22 same with Humana and Silverscript." 24 What are Humana and

Silverscript?

Page 193 1 Humana is a health plan. Silverscript is also a Medicare Part D 2 3 health plan under CVS. And just for clarification, when you say Medicaid Part D, what did you mean by that? Medicare. Medicare. What is that? 8 9 It's the, in the Medicare program, the Part D component of it is what 10 11 provides prescription drug coverage for 12 Medicare beneficiaries. 13 Then you say "NAMs and RAMs." That's, again, just to be clear, national 14 15 account managers and regional account managers? 16 17 That's correct. 18 ο. "NAMs and RAMs were informed yesterday and I coached them to speak to 19 their accounts." 20 21 Do you see that? 22 Yes, I see that.

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When you say in this e-mail "I

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1 in turn then speak to their customers, or who exactly are you talking about? 2 3 Yeah, so they would -- the RAMs and NAMs, their accounts were Humana and Silverscript and others like that. Oh, I see. So you talked to 6 7 other Forest people, and, as you put it, coached them to then talk to the outside 8 9 customers; is that correct? Α. Correct. 10 11 And then you continue on about MHA, and you say "Have a plan for them. 12 13 Would be taking admin fee and chargeback 14 percentage and move some of that to rebate 15 for their member pharmacies to help convert 16 17 Do you see that? 18 Yes. Α. 19 Good idea, I think. "Draws attn" -- that means 20 21 attention, correct? 22 Α. Correct. -- "to XR and saves us some 23 24 money. MHA may not like it, but they're doing little for us anyway." Veritext Legal Solutions

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coached them to speak to their accounts,

you mean you spoke to the NAMs and RAMs to

The plan that you are referring to is the same plan that earlier e-mail chain was talking about, correct?

> Α. Correct.

You can put that aside, sir. (Devlin Exhibit 25 marked for

identification )

Sir, what I have marked as Exhibit 25 bears Bates number FRX-AT-03793470.

It is titled Namenda Tablets. Discontinuation of Sale, Sales Force Training, Webex - Tuesday, February 18,

Do you see that, sir?

Yes, I see that. A

Have you seen this document

18 hefore?

I don't believe so.

Did you have any involvement in training of the sales force as of this date going forward with respect to the discontinuation plan for IR?

24 Ά No. I did not.

Do you know who would have been

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It states "We are communicating the withdrawal immediately and over the next six months."

Then it states "Over 150,000 physicians will receive letters, e-mails and all our messages. Over 200,000 pharmacists will receive letters, e-mails and chain announcements." And then it continues. Do you see that?

> Α. I do.

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Other than looking at this document, were you familiar with the scope of the communication plan and program that Forest initiated with respect to -- with respect to withdrawal of IR?

Like I said before, I knew we had a broad communication campaign. I wasn't familiar with the exact scope of numbers, 150, 200,000. I just knew we were communicating to all stakeholders.

All right. You can put that document aside, sir.

Just one more question on that document, 3494, if you look at Bates page 3494. Tell me when you're there, sir.

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Page 198 1 Α. Okay. 2 ο. Are vou there? 3 Do you know what POA stands for? Plan of action. Thank you. All right. You can 6 put that document aside. 8 Do vou know what the 9 abbreviation SCRAM stands for, S-C-R-A-M? 10 Α. Yes. 11 What does it stand for? 12 I believe it is senior care 13 regional account manager. And would you have had any 14 ο. 15 responsibility communicating with them? Yeah, I may have. 16 17 (Devlin Exhibit 26 marked for 18 identification.) 19 ο. We have marked as Exhibit 26. it bears Bates number FRX-AT-03801380. 20 21 It's an e-mail from a Ermie Fan dated 22 February 18th, 2014, with attachment, and 23 it starts with "Dear SCRAM Team," SCRAM,

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all capital letters.

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Do you see that, sir?

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- Α T see it
- Now looking at this document and seeing SCRAM, do you understand that SCRAM has the meaning you just testified
  - Α
  - 0 And who is Ermie Fan?
  - It is Emmie Fan.
  - I'm sorry, Emmie.
- That's all right. She worked on the Namenda brand team.
- Were you familiar with this kind of communication attached going to skilled nursing faculty staff?
- 15 MR. TOTO: With this particular 16 one?

MR. SORENSEN: Or something

like it.

18 19

MR. TOTO: I object to form.

- Yes. I'm familiar with it. Α.
- So she writes to others -well, who are these people who are the recipients of this? Do they have a particular job in common with each other?

Yeah, they were the SCRAMs.

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Page 200 1 Is that the to -- I'm sorry, go ο. ahead. 2 3 Under to, the SCRAMs were Cloonan, Roth, Desautels, Bley managed 5 them, and Sheldon managed Bley. 6 And the CCs, are they different types of folks? 8 Α. I'm not really sure who Jade 9 Jacqueline D'Onofrio was on the 10 brand team. Jason Wong was in the Payor 11 Marketing Group, as was Ellis and Williams. 12 Peter Maher I believe was on the brand 13 team, and Will Kane, brand team. 14 In the body of this, it says, 15 under "Dear SCRAM Team," there is a paragraph that starts "Furthermore." 16 "Furthermore, the Namenda Brand 18 Team has begun sending out communications 19 to a wide range of HCPs and caregivers, including the LTC audience, starting 20 21 today." What does HCP stand for? 22 23 Healthcare practitioner. 24 Other than dealing with your folks and clients, the managed healthcare

Page 209 1 being reported inside Forest? 2 Α. No. 3 You weren't aware of it? No, I was aware that we were seeing rapid increases in our Namenda XR 6 business primarily because of the changes 7 we made, improvements we made in Medicare Part D access and the changes that we made 8 9 in terms of sales force compensation, sales force promotion. That's what I recall. 10 11 12 Were you copied on reports 13 following February -- let me start again. Following the February 14th 14 15 announcement -- let me start one more time. Following the February 2014 16 17 announcement of the withdrawal of IR, were you regularly copied on internal Forest 18 19 reports tracking the transition from IR to 20 21 Before that date as well, yes, 22 and after that date. 23 Right. I'm just focused on after that date. You were copied on 24 reports after that date?

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Page 210 1 2 You can put that aside, sir. ο. (Devlin Exhibit 30 marked for 3 identification.) 5 Sir, I have marked as Exhibit 30, it's a document Bates numbered 6 FRX-AT-04038657. It has a metadata appendix attached to it. The metadata 8 9 appendix states a document date of and a creation date of April 29th, 2014. 10 11 Do you see that, sir? 12 Yes. Α. 13 And it says "File Name: SCC Notes 4-30." Sender/author is named Julie 14 15 Snyder. Do you see that? 16 Yes. 17 Julie Snyder, that's someone 18 you identified earlier, correct? 19 Correct And what does SCC stand for; do 2.0 21 you know? 22 Senior Commercial Committee. Α. 23 And what is that? 24 It's a -- it's a committee that was established by Bill Meury of a bunch of Veritext Legal Solutions 212-267-6868

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senior people in the various brand teams as well as Sales, Managed Markets, Compliance and --I'm sorry? Compliance, and other departments that were involved in commercialization of our products. And was the SCC something that preexisted -- well, let me start again. Do you know when the SCC first came into existence? I don't recall, no. 12 A Do you know how many members it had. 2. 10. 20? 15 Α. It varied from meeting to meeting. It was not a set committee. 16 Then the attached notes talks about performance. Number 1, it says "Conversion remains on the upswing." Do you see that? 20 Α. Number 2, below that, it says

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Page 212 1 and now has increased each week since end 2 of February and is at over 1,000 new XR writers per week." 3 Do you see that? 5 6 Then down below that, under Driving Conversion, it says "Just to touch on a few initiatives that will help us 8 9 continue to drive conversion to XR." 10 Underneath, it says that --11 underneath that, it says "The 12 discontinuation communications continue to 13 go out to physicians, caregivers and pharmacies weekly (caregivers) and monthly 14 15 (physicians)." 16 Do vou see that? 17 Yes, I see that. 18 All right. You can put that 19 aside, sir. MR. SORENSEN: Let me take a 20 21 short break. I'm very close to being done. THE VIDEOGRAPHER: We are going 22 23 off the record at 2:10 p.m. 24 (Recess taken.) (Devlin Exhibit 31 marked for

"New Namenda XR writers are over 1,000 per

week." Below that, it says "Was trending

around 700 or so for several weeks/months

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A. Yes.

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Q. Then if you scroll to the right there, the second-year total, it shows over \$48 million of profit share for Forest in the second year under this Lexapro generic analysis, correct, sir?

A. Yes.

Q. And you have no reason to doubt the accuracy of this spreadsheet, correct?

A. No reason to doubt it.

Q. Okay. Switching topics, throughout your testimony today, a couple of times you used the term "access." Do you recall that?

A. Yes

Q. You talked about Part D access and plan access. Do you recall that?

A. Yes.

Q. Can you explain what you mean by access?

A. Yeah. Access is a term that refers to formulary coverage, and, you know, the health plans and payors generally are in commercial markets or Medicare Part D, as the case with Namenda, because they

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had a large percentage of the business, a large majority that is paid for through the Medicare Part D program, and there's just a small number of approved plan sponsors that we negotiate with for formulary coverage or access to our products.

If you don't have that access, you get literally no business in Medicare. And if you have that access, you get a lot of business. So you have to, in order to gain that access, you have to negotiate and discount your price, and those companies are very formidable negotiators. That's their sole job, is to negotiate the lowest price possible for them and the highest discounts or rebates back from the manufacturer.

Q. And did you in fact negotiate with these plans to gain access for Namenda  $\ensuremath{\mathtt{XR?}}$ 

A. We did. We did. They were -those plans, the access and our success
came on over time, and the largest Medicare
plan sponsor we were able to gain access in
January of 2014, which had a large impact

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on our Namenda XR uptake.

- Q. And who was that plan?
- A. That was United Healthcare

  AARP, some may call it Optum, you may see
  it Optum in the spreadsheet, that's the

  PBM, but it is all owned by United

  Healthcare, which has the large majority of

  Medicare beneficiaries.
- Q. Can you describe how the concept of access is related to formulary coverage?

 $\label{eq:mr.sorensen: I will just note} \mbox{an objection.} \quad \mbox{This is outside the scope of} \mbox{the 30(b)(6).} \mbox{ But go ahead.}$ 

 $$\operatorname{MR}.$$  TOTO: It is certainly in the scope of what you asked him. Go ahead.

that, too. I'm not stopping you from testifying, I'm just noting objections. Go

A. Yeah, so those companies such as United AARP or Silverscript or Humana that I had testified to maintain a formulary, and there can be products on that formulary that are preferred by that

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plan sponsor, and preferred means that's the product that they receive the best price for, the product that they then charge the lowest out-of-pocket co-pay for the patient, or they can have a product that will be nonpreferred brand, which will have a higher co-pay for the patient.

They can put restrictions in place and barriers to physicians prescribing one product over another through generic step requirements at the point of sale, prior authorizations from physicians, or they can choose to simply not cover the product and force the patient, the Medicare patient to pay full price and reject it.

Q. Do plans negotiate for preferential pricing in the form of discounts in return for preferential formulary placement?

Yes, they do.

A. Yes

MR. SORENSEN: Same objections.

Go ahead.

Q. And did you in fact have those

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MR. SORENSEN: I disagree with

ahead.

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Page 257 irrelevant. We never -- we never limited physician or patient choice to IR, XR, any

form of Namenda, memantine. We were not allowed -- we were prevented from implementing any withdrawal, so it becomes

irrelevant.

Q. And do you recall there were questions, and in this document there was something called an acceleration factor?

 ${\tt A.} \qquad {\tt Yes, \ Counselor \ had \ asked \ me}$  about that.

Q. Do you believe the February

14th announcement of the then plan to
withdraw Namenda IR caused an acceleration
in conversion?

MR. SORENSEN: Objection, leading. Objection, this witness has already demonstrated he can't answer that question with knowledge, he is an inadequate witness. But go ahead.

A. Well, I object to what the Counselor just said. I think I have a high degree of competence about my job responsibility, as evidenced by my record over 30 years.

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And in my estimation, with the majority of the market being in Medicare Part D and the largest player in Medicare Part D restricting access to Namenda XR prior to January of 2014, we had a slower time then in getting business.

Once we changed that and opened up preferred brand low co-pay access at United Healthcare in January of 2014, that was a major accelerant to our conversion. That along with the sales force changes, putting more resources, efforts, and changing the sales force compensation to 100 percent on the Namenda XR, allowed us to optimize that message and the reimbursement and formulary coverage, and those were catalysts and accelerants that, in my estimation, were responsible for the increase in conversion rate.

20 And the other thing, I'm going 21 to say it --

Q. Go ahead.

A. It is part of my testimony,

Namenda XR was an innovative product

improvement. It was memantine dosed once a

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day, and we specifically priced it at a lower price to payors and obtained formulary access so the price out of pocket for the patient was the same or less than Namenda IR.

It was a fantastic product. We put a lot of money, effort and resources behind the conversion in how we promoted it and how we priced it, and for every prescription that we moved from Namenda IR to Namenda XR, it was a lower price and we didn't make as much money, but the patients and caregivers benefited because it was convenient.

That was part of the progression and the story and the innovation of the molecule, of memantine.

We started with evidence and data that told us combination therapy was more effective than any product used by itself, and so we launched originally with twice-a-day memantine, which is Namenda IR. We innovated and improved that to make it more convenient in once-a-day dosing in Namenda XR, and ultimately launched the fixed-dose

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combination, which, as I stated, the clinical evidence supports that as the treatment standard, and that was donepezil and memantine once a day in one pill, the ultimate convenience for the caregiver and the patient, and we did it at pricing for Namenda XR and Namzaric that was less than Namenda IR.

MR. SORENSEN: Move to strike that entire speech as nonresponsive and beyond the scope.

(Devlin Exhibit 37 marked for identification.)

Q. Do you have Exhibit 37 in front of you, sir?

MR. TOTO: And I oppose the motion to strike.

Q. Do you have that exhibit in front of you?

A. I do.

Q. You see this is an e-mail chain, the top e-mail is dated December 18th, 2013?

A. Yes

Q. Now, by definition, that's just

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prior to the January or early 2014 period that you just mentioned, correct?

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And if you go to the attachment to the e-mail chain, you see the heading says "Great News! Key Namenda XR Wins: Four New Formularies Added."

Do vou see that?

- I do.
- ο. And you received this e-mail and attachment in the ordinary course of business; is that correct?
  - That's correct.
- And can you explain what this 14 15 attachment is summarizing?
  - Yeah, it's an announcement to the sales team. It is summarizing the Medicare Part D formulary coverage that changed as of January 1st, 2014, and the national accounts listed down the left side of the table of the document are in descending order of the importance of those Medicare Part D plan sponsors or health plans in terms of the percentage of market volume that they account for.

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1 And so this document is 2 speaking to the changes and the improvements in access that my team was 3 able to generate through negotiations and heavy discounts to these health plans to where we were able to gain preferred brand access for Namenda XR with Optum/United Healthcare AARP, which is the largest Part 8 9 D plan sponsor, representing over 25 percent of all volume for Namenda IR. 10 11 We also gained access at Aetna, 12 WellPoint Anthem and Prime Therapeutics. 13 which are also strong Part D plan sponsors, 14 in the top ten list of all those plan 15 sponsors. So it was a major change in access, and we were announcing that to the 16 17 sales force. 18 Q. Based on your experience and 19 your work in this area, did these wins 20

accelerate conversion to Namenda XR from Namenda IR?

22 MR. SORENSEN: Objection, 23 leading. Objection, beyond the scope.

Yes, without a doubt.

25 Would those -- would that

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acceleration be felt immediately as of January 1st, 2014 or would it accelerate over time?

MR. SORENSEN: Same objections.

There usually is -- it could be a few weeks or a month or so lag. It's not precise to the first day of the month.

Medicare patients oftentimes will move in and out of plans or change plans. There is a little bit of disruption, sometimes confusion at the change of the benefit year, which is January 1st. Sometimes there are deductibles that the patients have to pay and work through in the early couple of months

So there could be a little bit of a lag in terms of when you start to see effect, not much, but --

Okay. Now, Mr. Sorensen asked you a lot of questions about the period 2014 and earlier, right?

Α.

ο. He didn't really ask you any questions about after the injunction, in HIGHLY CONFIDENTIAL

Page 264

1 other words, you know, after December 2014 into 2015; is that right? 2

MR. SORENSEN: Objection,

leading. Go ahead.

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That's about right.

MR. TOTO: I think the record will reflect that.

MR. SORENSEN: It doesn't make it not leading.

Now, after the injunction issued, is there any reason that a patient that was on XR at that point in time couldn't switch back to Namenda IR prior to the loss of exclusivity of Namenda IR?

MR. SORENSEN: Objection,

leading, beyond the scope. 16

> No. I think as I testified before, the patients had, and physicians, had the choice, they could have changed from XR back to IR if they wanted to, or IR to XR, both were available, there was no -there was no withdrawal. There was no limited distribution or restriction of any kind

> > After the injunction issued,

Page 269 1 2 Q. And did Forest make some effort to send out communications to all its 3 stakeholders telling them about the lawsuit by the New York Attorney General? Α. I don't recall if we sent out 7 letters to stakeholders informing them. I recall having conversations with my 8 9 customers about it. ο. My question was, did it send 10 11 out thousands and thousands of e-mails and other forms of communication announcing 12 13 that the New York Attorney General had sued 14 it? 15 No, I'm not aware of that. 16 The injunction that you were 17 asked about was issued when? Α. I believe that was in December 18 19 of 2014 20 So approximately what, ten 21 months or so after the announcement of the 22 withdrawal of IR, correct? MR. TOTO: I object to form, 23

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ο.

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Well, you testified about an

assumes facts, lacks foundation.

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Page 270 1 injunction, correct? Α. Correct. 2 3 You also testified earlier about a press release announcing Forest's announcement of the withdrawal of IR which was dated in February 2014, correct? Correct The difference between, in 8 9 days, between February 2014 and December 2014, is approximately ten months, correct? 10 11 12 MR. TOTO: Your prior question 13 said withdrawal, which we established never happened, so try to ask a precise question, 14 15 Counsel. MR. SORENSEN: Move to strike 16 17 your commentary and testimony, Counselor. 18 Q. Now, after Judge Sweet's opinion issuing the injunction, we can take 19 a step back, have you ever read Judge 20 21 Sweet's opinion? 22 Α. His complete opinion, I do not 23 believe I have read that. 24 Did Forest make any effort to send Judge Sweet's complete opinion to its

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#### HIGHLY CONFIDENTIAL

Page 271 1 thousands of potential customers -- let me 2 3 Did Forest make any effort to distribute copies of Judge Sweet's opinion 5 to its customers? 6 MR. TOTO: Objection, relevance 8 Go ahead. 9 Not to my knowledge. 10 In communicating with 11 customers/stakeholders after the injunction was issued, isn't it correct that Forest 12 13 noted in such letters that it was appealing that decision? 14 15 Α. In such letters to whom? To -- well, I could show you 16 ο. 17 some of them, and I guess I will if you 18 don't remember this, but in sending out 19 letters to stakeholders of various types, didn't Forest note that it was appealing 20 21 the injunction? MR. TOTO: We have to clarify 22 23 the time frame here, because that's not 24 clear Can you answer that question?

#### HIGHLY CONFIDENTIAL

Page 272 1 MR. TOTO: Vague as to time. I don't -- I don't know about 2 the document. I will be happy to look at 4 5 Okay. I will show you something about that. 7 (Devlin Exhibit 38 marked for 8 identification.) 9 Sir, I have marked as Exhibit 10 38 a document that bears Bates number FRX-AT-04288486. 11 12 It's an e-mail and attachment 13 dated January 13th, 2015. Do you see that? Yes. I see it. 14 15 And you see attached to this is two form letters. If you look at Bates 16 17 page 8490, "Dear Customer." 18 Tell me when you're there, sir. 19 I am there. It says "Dear Customer: Forest 20 21 Laboratories, a wholly-owned subsidary of Actavis, Inc., plans to continue the sale 22 of Namenda (memantine HCL) tablets in 24 accordance with a court order, which we are appealing."

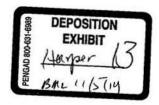
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## EXHIBIT 282

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY PURSUANT TO PROTECTIVE ORDER

# IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK	) CASE NO. 14-CV-7473 (RWS)
Plaintiff,	)
v.	(
ACTAVIS, PLC et al,	)
Defendants.	)
	}



### DECLARATION OF

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY PURSUANT TO PROTECTIVE ORDER

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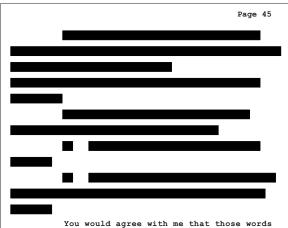
Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 40 of 171

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY PURSUANT TO PROTECTIVE ORDER

# EXHIBIT 285

	Page 1
1	IN THE UNITED STATES DISTRICT COURT
2	SOUTHERN DISTRICT OF NEW YORK
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5	
6	IN RE: NAMENDA DIRECT
7	PURCHASER ANTITRUST   C.A. 1:15-cv-07488-CM
8	LITIGATION
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12	** HIGHLY CONFIDENTIAL **
13	
14	Videotaped oral deposition of NATHAN HERMANN,
15	MD, called by the Forest Entity Defendants herein,
16	held before a stenographic court reporter at the
17	offices of Lenczner Slaght Royce Smith Griffin LLP,
18	130 Adelaide St. West, Ste. 2500, Toronto, Ontario,
19	on Thursday, the 2nd day of November, 2017, at 9:00
20	a.m.
21	
22	
23	
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don't appear here on page 8 in the construction of "treatment of cerebral ischemia," right? By "those words," I mean "achieving therapeutic effects."

A. So, "treatment of cerebral ischemia" and "antagonistic intervention with regard to NMDA receptor channels," if you look at claim 7, "reconstructed" -- or, sorry, the construction on point 7: (as read)

"The term 'imbalance of neuronal stimulation after -- excuse me -- after Alzheimer's disease' means a pathophysiological situation

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### HIGHLY CONFIDENTIAL

Page 46 1 characterized by an excessive 2 inflow of calcium through the NMDA 3 receptor channel." (Query by reporter) 5 Sorry. (Query by reporter) Sorry. (as read) 8 "The term 'imbalance of neuronal 9 stimulation after Alzheimer's disease' in claim 17 means a 10 11 pathophysiological situation 12 characterized by an excessive 13 inflow of calcium through the NMDA receptor channels after Alzheimer's 14 15 disease." 16 And then goes on to state that "the term 17 imbalance of neuronal stimulation" -- so these are, 18 again, using the same terms after Alzheimer's 19 disease in claim 17: (as read) 20 "-- means an antagonistic 21 intervention with regard to the 22 excessive inflow of calcium through 23 NMDA receptor channels after 24 Alzheimer's disease." 25 The fact that he continuously refers to

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### HIGHLY CONFIDENTIAL

### Page 47

Alzheimer's disease here is to me an indication that this is for a therapeutic benefit.

- $\label{eq:Q.Mm-hm.} \mbox{Does the same hold true for}$  the claim term "effective amount"?
- A. It would be an "effective amount" to treat Alzheimer's disease by antagonizing the NMDA receptor.
- Q. Mm-hm. So "achieving therapeutic effects," that's part of "effective amount" as well?
  - A. Yes.
- A. Actually -- sorry, to interrupt, but if you look at the "effective amount" term, he -- the constructed claim says "an amount shown to cause improvement in comparison to placebo."
  - Q. Mm-hm?
- A. So there's clearly a linkage of "effective amount" to improvement.
  - Q. Mm-hm. And the --
  - A. Or to therapeutic effect.
- Q. Okay. Now, I was asking you about the term "treatment of cerebral ischemia." And you started answering me with reference to the term "imbalance of neuronal stimulation after Alzheimer's

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disease."

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Now, that term "imbalance of neuronal stimulation after Alzheimer's disease," that's not one of the terms you identified in paragraph 33 of your report as non-infringed, right? I'm in paragraph 33 now, Dr. Herrmann, not 36. I think it's set out more clearly there in 33. 33 says:

(as read)

"Forest wouldn't have been able to prove that Mylan infringed three claim terms. Those terms were "the prevention or treatment of cerebral ischemia," the "treatment of cerebral ischemia," and the 'treatment of neuronal stimulation after Alzheimer's disease '"

Right? Those are the three terms you identified in paragraph 33, correct?

A. Correct

# EXHIBIT 287

	Page 1
1	** HIGHLY CONFIDENTIAL **
2	UNITED STATES DISTRICT COURT
3	SOUTHERN DISTRICT OF NEW YORK
4	Civil Action No. 1:15-cv-07488-CM
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	IN RE NAMENDA DIRECT PURCHASER
7	ANTITRUST LITIGATION
8	
9	x
	October 26, 2017
10	8:58 a.m.
11	
12	
13	Videotaped Deposition of GEORGE W.
14	JOHNSTON, JR., taken by Defendants,
15	pursuant to Notice, held at the offices of
16	Gibbons, P.C., One Gateway Center, Newark,
17	New Jersey, before Todd DeSimone, a
18	Registered Professional Reporter and Notary
19	Public of the State of New Jersey.
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Page 133 1 \_\_\_\_\_ 9 Q. Okay. 10 Α. Fair enough? 11 I understand your position. 12 Α. Sounds good. 13 And enablement is a conclusion of law, right?

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Page 134
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                 As I understand it, yes. But,
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    again, for clarity, we had two enablement
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    arguments. One was the unproven
    hypothesis, and the other one was did they
    enable the full scope.
 6
                 I got it.
7
                 And I assume you are talking
    about the unproven hypothesis approach that
8
9
    we have articulated in this report, in my
10
    report.
11
                 Well, all I've asked you so far
12
    is just whether enablement is a conclusion
13
14
         Α.
                 Okav.
15
                 And your recollection is that
    it is, right?
16
17
         Α.
                 Right.
18
         Q.
                 So when you are opining that
    Mylan was likely to prevail on enablement,
19
    you are reaching a legal conclusion there,
20
21
    right?
22
                 MR. CHORUSH: Objection.
23
                 No, I don't think so.
         Α.
                 Why not?
         Ο.
                 I'm going to leave that to the
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Page 135

judge.

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What I'm suggesting is, again, I go back to what it is I was asked to do, I was asked to basically handicap for management of each one of these companies what's the likelihood of success at the time of settlement, and whether the judge agrees with me or not is really not relevant.

The whole point is what I felt as a reasonable patent attorney sitting in a room with management and advising them as their chief patent counsel, and based upon that, my assessment simply was that for both enablement arguments, since we're not speaking for one of them, that both of them were at 60 percent, and I hope I got the numbers right this time.

Q. I don't even remember, to be

honest with you.

But I guess so we are in that, let's pretend we are in that board room, right, and this hypothetical reasonable and competent patent lawyer is advising the management of either Forest or Mylan about

Page 136

the likelihood of success on enablement, okay?

A. Fair enough.

Q. They are advising their clients on the likelihood that a court will reach a particular legal conclusion?

A. No. They are asking for my opinion based upon my professional judgment, what's the likelihood of success.

A. That's fair. That's fair.

Q. And on enablement, it's a question of law, so it is the likelihood of success with regard to a particular legal conclusion, right?

A. Well, it's applying the law to the facts and to the differences in the facts between the two parties, and then the additional secret sauce of my putting my professional judgment into the mix to come out with a percentage.

Q. I understand.

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Do you think you are more qualified than Judge McKelvie to opine on the likely outcome of the '703 patent litigation were there a trial?

Let me, if you don't mind, let me rephrase that a little bit based on what I was asked to do.

Going back to what I was asked to do is to consider what a reasonable patent attorney would do to come up with some sort of a quantifiable number in terms of overall likelihood of success, which could be communicated to the client, either of the two litigants, at the time of settlement. And I do think -- I know that

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Covington & Burling for a number of years. I don't know specifically how many clients he was involved with at that time as related to patent litigations. I don't know if his clients asked him to opine on those type of things. Normally those questions are handled by inside counsel. They are the type of questions that a chief patent counsel would be required to provide information to senior management.

Okay.

So I guess the answer is no, I think I would be better qualified with regard to that specific issue.

Okay. Can you remind me, sir, Q. of your undergraduate degree?

Yeah. I received a bachelor of engineering, concentration in chemical engineering, from Stevens Institute of Technology in Hoboken.

Do you think your technical background in terms of your undergraduate degree makes you better suited than Judge McKelvie to opine on the issues in this case?

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I would be more qualified than Judge McKelvie because that's what I did at Roche. That was one of the aspects that was my job for 16 years.

You don't think Judge McKelvie has extensive experience counseling clients on the potential outcome of a pending patent litigation?

Α. Well, let's see what he says.

I don't think we have marked Q. his report as an exhibit yet, so can you answer that without looking at his report?

If you want me to, but I prefer to have the best information in front of

Let's try for now to do it without his report.

Α. Okay. And if you would be 19 gracious enough to repeat the question.

Sure. The question was you don't think Judge McKelvie has extensive experience counseling clients on the potential outcome of a pending patent litigation?

Well, I understand he worked at

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And "these issues," we are talking about likelihood of success, just to make sure we're on the same page?

I do, in conjunction with my experience of 36 years at Hoffmann-LaRoche interfacing on a regular basis with the scientists, yes. My understanding is, and, again, without looking at the report, that Judge McKelvie has no scientific background whatsoever.

ο. And the judge who would have decided the '703 patent case did not have a technical background either, did he?

> Α. Judge Sleet?

ο. Yes

I don't know. I just don't

18 know



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Page 173 \_\_\_\_\_

I'm going to ask you a couple of similar questions though.

Sure.

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- Would you agree with me that Q. you did not have the specialized technical expertise required to opine on what a person of ordinary skill in the art understood about memantine in 1989?
- Let me just clarify. Again, it goes back to why I was there, not to be a technical expert, but review the evidence established by the technical experts and make a determination of what a reasonable patent attorney would do.

Now, probably you are going to ask me similar questions, so instead of me repeating that each time, if you do ask me similar questions, please consider that that's the thrust, that I had a different

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role than that of the technical experts. I had a very focused role in terms of what a reasonable patent attorney, often considered, say, a chief patent counsel, because we did it all the time, would have perceived as the likelihood of success at the time of settlement.

- And one of the issues on which you rendered an opinion as to the relative likelihood of success of Forest and Mylan was the issue of infringement, right?
- 12 Yes. I did.
- And you would agree with me that if the '703 patent litigation had gone 14 15 to trial it would have been technical experts that testified on the issues of 16 infringement, correct?
  - Yes, technical experts would be the ones who presented the evidence to Judge Sleet to make a determination on.
  - The same with validity, correct?
- 24 And your expertise, sir, is patent law; is that correct?

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MR. CHORUSH: Objection.

- Patent law -- I've got to slow down -- patent law, licensing, my expertise based upon being a chief patent counsel for 16 years at a major pharmaceutical organization whereby on a regular basis we would do these interpretations of likelihood of success. I should say perceived likelihood of success. We would do the handicapping.
- ο. Sure. You're not an economist, correct?
- You don't have any degrees in economics that I'm not aware of?
  - No. sir A
- You don't have any expertise in economic modeling?
  - Α. No, I do not.
  - You don't consider yourself qualified to testify as an expert regarding economics, do you?
    - You are correct. Α.
- Ο. And just to, because I have it written here, you didn't do any economic

modeling in this case, did you?

- Absolutely not. That was not what I was asked to do.
- I understand. Do you plan to testify at trial in this case?
- I will testify at trial if asked to do so.
- And if you are asked to do so, do you plan to testify about patent law?
- Well, what I plan to testify would be, number one, what I'm asked to do in terms of at that time, and, number two, is I believe it would have to be consistent with what's in my briefs, I should say my report, the opening report and the reply report.
- So that means I would be testifying on three or four items, the likelihood of success, the timing, the cost, and I'm sure I'm forgetting one, but I think you got the drift. It is all identified in the report.



# EXHIBIT 290

	Page 1
1	UNITED STATES DISTRICT COURT
	SOUTHERN DISTRICT OF NEW YORK
2	Civil Action No. 1:15-cv-07488-CM
3	
4	IN RE NAMENDA DIRECT PURCHASER
	ANTITRUST LITIGATION
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11	VIDEOTAPED DEPOSITION of ROBERTO
12	MALINOW, M.D., Ph.D., taken at White &
13	Case, 1221 Avenue of the Americas, New
<b>14</b>	York, New York at 9:11 a.m., Wednesday,
15	November 8, 2017, before Debra Stevens,
16	Certified Realtime and Registered
17	Professional Reporter and Notary Public of
18	the State of New York.
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# Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 51 of 171

R. MALINOW, M.D., PH.D.

	K. MALINOW, M.D., FH.D.	
		Page 21
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	• •	
5	Q. And you have reviewed their	09:30
6	reports and CV's. Correct?	09:30
7	A. Yes, I did.	09:30
8	Q. You are aware that both of them	09:30
9	have been practicing medicine for the	09:30
10	treatment of Alzheimer's disease for more	09:30
11	than 10 years. Correct?	09:30
12	A. I believe so. I don't remember	09:30
13	exactly the number of years that they have	09:30
14	been doing this, but I know that they have	09:30
15	been practicing for a number of years.	09:30
16	10 years is probably a reasonable guess.	09:30
17	Q. You would agree that Dr. Herman	09:30
18	is a clinical expert in the treatment of	09:30
19	Alzheimer's disease. Correct?	09:30
20	MR. JOHNSON: Objection.	09:30
21	A. He is I mean, he's a	09:30
22	clinician and he I believe he treats	09:30
23	patients with Alzheimer's disease, and so	09:31
24	I assume he could be considered an expert	09:31
25	in that field.	09:31

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R. MALINOW, M.D., PH.D.

Pa	ige 22
Q. Similarly, you would agree that	09:31
Dr. Schneider strike that.	09:31
You would agree that	09:31
Dr. Schneider is a clinical expert in the	09:31
treatment of Alzheimer's disease.	09:31
Correct?	09:31
MR. JOHNSON: Objection.	09:31
A. I think that it's basically the	09:31
same question, so I will give the same	09:31
answer. Whatever I said for Dr. Herman, I	09:31
will say or I will let you write whatever	09:31
I said for Dr. Herman, I also mean for	09:31
Dr. Schneider.	09:31
Q. Well, the answer for Dr. Herman	09:31
was yes, he is an expert clinician.	09:31
Correct?	09:31
MR. JOHNSON: Objection.	09:31
A. I don't think I said those words	09:32
exactly in that order, but generally the	09:32
meaning was, yes, he's practiced medicine	09:32
sufficiently and treated patients for	09:32
Alzheimer's so as to be considered an	09:32
expert.	09:32
Q. Do you have a laboratory?	09:32
A. I run a laboratory, yes.	09:32

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### R. MALINOW, M.D., PH.D.

Pa	age 23
Q. Have you ever used memantine in	09:32
any study or experiment in your	09:32
laboratory?	09:32
A. We have used it. We have never	09:32
published a paper with it. We have	09:32
published papers with compounds that are	09:32
not too dissimilar to memantine.	09:32
Q. What compounds, in your view,	09:32
are not too dissimilar to memantine?	09:32
A. Well, I would say that MK-801,	09:33
although I would say that there is	09:33
significant differences, it has some	09:33
similarities. And we have used magnesium,	09:33
which again has some similarities but also	09:33
some differences.	09:33
Q. Describe for me the experimental	09:33
work that your laboratory has undertaken	09:33
with respect to memantine.	09:33
A. As I mentioned, it was	09:33
unpublished, and I'd have to think about	09:33
that because that was probably some	09:33
20 years ago. And what were we doing? I	09:33
think the results were inconclusive and	09:34
so, you know, I wouldn't be able to tell	09:34
you what the results were.	09:34

R. MALINOW, M.D., PH.D.	
	Page 24
Q. What was being studied?	09:34
A. Something about synaptic	09:34
transmission. I can tell you that. That	09:34
is all I was studying at the time.	09:34
Q. Is that the only instance that	09:34
you can recall in which your laboratory	09:34
undertook studies relating to memantine?	09:34
A. Well, when you say "relating to	09:34
memantine," or are you asking using	09:34
memantine?	09:34
Q. Using memantine.	09:34
A. Okay. Those are the only	09:34
studies that I can remember where we used	09:34
memantine, but there are a number of other	09:34
studies in some ways related to memantine,	09:34
that we were using these drugs that I	09:35
mentioned to you.	09:35

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R. MALINOW, M.D., PH.D.	
	Page 193
<b>-</b>	
Q. So, you write, about six lines	15:23
or seven lines from the bottom of	15:23
paragraph 64, so about halfway in the	15:23

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middle -- in paragraph 64 of your 2017 15:23 report you write, "A person of ordinary 15:23 skill in the art in April 1989 would have 15:23 known that overstipulation of NMDA 15:23 receptors causes an excess of calcium 15:23 entry and neuronal death and therefore 15:23 would have understood, based on the 15:23 disclosures of the '703 patent, that the 15:23 mechanism of action for memantine's 15:23 neuroprotective effect results from its 15:23 NMDA receptor antagonism." 15:24 Do you see that? 15:24 A. Yes. 15:24 So is it your opinion that at 15:24 the target daily dose memantine provides a 15:24 neuroprotective effect by antagonizing 15:24 NMDA receptors? 15:24

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R. MALINOW, M.D., PH.D.

	Pag	re 194
1	A. I believe that's the generally	15:24
2	accepted view.	15:24
3	Q. And is it your view?	15:24
4	A. My view is that of the generally	15:24
5	accepted view, generally.	15:24
6	Q. If you were correct that the	15:24
7	target daily dose of memantine provides a	15:24
8	neuroprotective effect, memantine would	15:24
9	slow neurodegeneration in Alzheimer's	15:24
10	disease patients. Correct?	15:24
11	A. Presumably. Now, again, I am	15:24
12	not a clinician, so I don't want to say	15:25
13	anything about relations between the	15:25
14	amounts of neuroprotection and the	15:25
15	progression of the disease. I don't want	15:25
16	to get into that at all.	15:25
17	But the idea, I believe, is that	15:25
18	neuroprotection is the basis of	15:25
19	memantine's action on Alzheimer's disease	15:25
20	patients.	15:25
21	Q. Let me reask my question without	15:25
22	the clinical trying to avoid the	15:25
23	clinical stuff.	15:25
24	A. Okay.	15:25
25	Q. Achieving neuroprotection would	15:25

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R. MALINOW, M.D., PH.D.

Paq	ge 195
slow neurodegeneration; correct?	15:26
MR. JOHNSON: Objection.	15:26
A. Is this in animals? In people?	15:26
I mean, I certainly know that in animals,	15:26
and I assume that would also be the case	15:26
in people.	15:26
Q. Well, I am really just trying to	15:26
piece together things you have told me.	15:26
But, in essence, you have told me	15:26
neuroprotection protects against neuronal	15:26
loss or death by limiting the flow of	15:26
calcium into the neuron. Correct?	15:26
A. That is one form of	15:26
neuroprotection. Yes.	15:26
Q. And that would, therefore,	15:26
save that would therefore spare neurons	15:26
from death. Correct?	15:26
A. Yes.	15:26
Q. And sparing neurons from death	15:26
would slow neurodegeneration. Correct?	15:26
A. Yes.	15:27
Q. So by definition,	15:27
neuroprotection would cause slowing of	15:27
neurodegeneration. Correct?	15:27
A. Yes. I think I agreed to that	15:27

R. MALINOW, M.D., PH.D.

R. MALINOW, M.D., PH.D.	
	Page 196
earlier, but yes.	15:27
Q. You know, one of the problems	15:27
with us lawyers is we have to have a clea	r 15:27
record. Sometimes and this is not to	15:27
criticize you, but when there are long	15:27
answers or I don't phrase a question the	15:27
way I might have wanted it, the record	15:27
isn't always completely clear.	15:27
A. Okay.	15:27
Q. Will you agree with me that the	15:27
most striking neurochemical disturbance i	n 15:27
Alzheimer's disease is the deficiency of	15:27
acetylcholine in the brain?	15:27
MR. JOHNSON: Objection.	15:27
A. That is a clinical question and	15:27
I don't feel comfortable answering that.	15:27
Q. Your laboratory has shown that	15:28
excessive amounts of beta amyloid decreas	se 15:28
glutamatergic synaptic transmission.	15:28
Right?	15:28
A. Yes.	15:28
Q. Glutamatergic synaptic	15:28
transmission includes, among other things	15:28
signal transmission through NMDA	15:28
receptors. Correct?	15:28

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R. MALINOW, M.D., PH.D.

K. WALINOW, W.D., FH.D.		
Page 197		
A. Yes.	15:28	
Q. During the course of the Namenda	15:28	
patent litigation, Dr. John Olney	15:29	
submitted a report on behalf of Mylan.	15:29	
Correct?	15:29	
A. Yes.	15:29	
Q. I am going to hand you a copy of	15:29	
Dr. Olney's report.	15:29	
MR. JOHNSON: Would you like to	15:29	
take a break? It's been about	15:29	
55 minutes.	15:29	
Q. Would you like a break?	15:29	
A. Let's do it now.	15:29	
THE VIDEOGRAPHER: Going off the	15:29	
record at 3:25 p.m. This marks the	15:29	
end of media 4.	15:29	
(Recess.)	15:48	
THE VIDEOGRAPHER: We are back	15:48	
on the record at $3:50\ p.m.$ This marks	15:50	
the beginning of media 5.	15:50	
Q. Dr. Malinow, I am handing you a	15:50	
copy of Exhibit 10.	15:50	
(So marked for identification as	15:50	
Plaintiff's Malinow Exhibit 10.)	15:50	

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15:50

Dr. Malinow, you recognize

Q.

R. MALINOW, M.D., PH.D.

	K. WILEINOW, W.D., TH.D.	
	Pag	e 198
1	Exhibit 10 as an expert report submitted	15:51
2	by Dr. Olney on behalf of Mylan in the	15:51
3	Namenda patent litigation. Correct?	15:51
4	A. Yes.	15:51
5	Q. And your supplemental report	15:51
6	submitted in 2010 responded to the Olney	15:51
7	report. Correct?	15:51
8	A. Yes.	15:51
9	Q. If I refer to Exhibit 10 as the	15:51
10	"Olney report," is that acceptable to you?	15:51
11	A. Yes.	15:51
12	Q. Dr. Olney has now passed away.	15:51
13	Correct?	15:51
14	A. Yes.	15:51
15	Q. Dr. Olney was an extremely	15:51
16	well-regarded expert on neuropharmacology.	15:51
17	Correct?	15:52
18	A. Yes.	15:52
19	Q. Dr. Olney's science group had	15:52
20	published numerous articles on NMDA	15:52
21	receptor antagonists. Correct?	15:52
22	A. Yes.	15:52
23	Q. Dr. Olney's group had published	15:52
24	several articles on the effects of	15:52
25	memantine. Correct?	15:52

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## R. MALINOW, M.D., PH.D.

	R. MALINOW, M.D., PH.D.	
	Pag	je 199
1	A. Yes. I should say that he	15:52
2	didn't he wasn't they didn't do much	15:52
3	electrophysiology, I should mention, which	15:52
4	is really the strength of my expertise.	15:52
5	But yes, he had done work with NMDA	15:52
6	antagonists, including memantine.	15:52
7	Q. The term "Olney lesions" is a	15:52
8	term named after Dr. Olney. Correct?	15:52
9	A. Yes.	15:52
10	Q. Dr. Olney also coined the term	15:52
11	"excitotoxicity" that is commonly used to.	15:53
12	Correct?	15:53
13	A. Yes.	15:53
14	Q. In your reports that you	15:53
15	submitted in the Namenda patent litigation	15:53
16	and in this litigation, you have not	15:53
17	identified any reason to doubt the	15:53
18	qualifications of Dr. Olney. Correct?	15:53
19	A. Not the qualifications, no.	15:53
20	Q. You disagree with some of his	15:53
21	opinions. Correct?	15:53
22	A. Right.	15:53
23	Q. Is it your opinion and I	15:53
24	understand that you agree with	15:53
25	Dr. Olney's some of his opinions at	15:53

R. MALINOW, M.D., PH.D.	
Pag	ge 200
least. Is it your opinion that	15:53
Dr. Olney's opinions as set forth in the	15:53
Olney report are unreasonable?	15:53
MR. JOHNSON: Objection.	15:53
A. I think you'd have to point to	15:54
something very specific, and then I would	15:54
tell you if there is a reason involved and	15:54
what it would be. I think that's a little	15:54
bit too vague, open-ended question.	15:54
Q. As you sit here right now, are	15:54
you aware of any opinions offered by	15:54
Dr. Olney in the Olney report that you	15:54
believe are scientifically unreasonable?	15:54
MR. JOHNSON: Objection.	15:54
A. Scientifically unreasonable?	15:54
Well, if I don't agree with them, does	15:54
that mean that I think they are	15:54
unreasonable?	15:54
Q. No. And I am not meaning to	15:54
suggest that. To be clear, I understand	15:54
that you disagree with a number of	15:54
Dr. Olney's opinions.	15:54
A. Yes.	15:55

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# EXHIBIT 292

	Page 1
1	UNITED STATES DISTRICT COURT
2	SOUTHERN DISTRICT OF NEW YORK
3	:
	IN RE NAMENDA DIRECT PURCHASER :
4	:No. 15-cv-7488-CM-JCF
	ANTITRUST LITIGATION :
5	:
6	Washington, D.C.
7	Wednesday, October 18, 2017
8	***CONFIDENTIAL***
9	Videotaped Deposition of:
10	RODERICK McKELVIE,
11	called for oral examination by counsel for
12	Plaintiff, pursuant to notice, at the office of
13	White & Case, LLP, 701 13th Street, N.W., before
14	SUSAN L. CIMINELLI, CRR, RPR, of Veritext Legal
15	Solutions, a Notary Public in and for the District
16	of Columbia, beginning at 9:06 a.m., when were
17	present on behalf of the respective parties:
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Page 49

Q. Did you ever enforce that rule by excluding expert testimony that was not properly described in an expert report?

A. I did, but I didn't -- I don't think I ever excluded an expert totally. I would draw a circle around what the expert's opinion was, and say that he or she may have wandered off what the report was, but I've seen cases reported now where judges exclude it. I saw that -- you've seen certain judges just exclude a witness entirely. It's like cutting off a gladiator's arm before a fight. It's not really a fair thing to do. I think what you want to do is allow the expert report in, but contain it to what reasonably put the other on notice about what the witness was going to say.

I do remember Judge Posner had his decision that was -- I think shocked a lot of

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lawyers in our community, where he excluded experts completely. You can go -- imagine trying to go to trial without your expert witness. It's going to very hard to do in patent litigation.

- Q. I think I understand what you've told me. I want to circle back and make sure. When you were a Federal District Court judge, you might allow an expert to offer clarification or additional description for an opinion that was explicitly set forth in his or her report, correct?
  - A. That's pretty correct.
- Q. But when you were a Federal District

  Court judge, you would not allow an expert to offer
  an entirely new opinion that wasn't set forth in his
  or her report, correct?
- A. I think -- I think that's the general practice that trial judges have, and lawyers should expect, is that you have some leeway when you go into a trial, to get an expert to explain his or her opinion.

It may be that that encompasses opinions that aren't explicitly set out in the report, but

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the other side's on fair notice of it. So we saw that with Malinow, that he -- Forest filed his report out of time, but gave the other side time to take his testimony. And the issue was still open with the judge when they went into the pretrial conference about whether Malinow would be allowed to testify to the matters included in his reply report, supplemental report.

- Q. So that was one of the uncertainties that the parties had at the time that they settled the Namenda patent litigation, correct?
  - A. That was one of the uncertainties.
- Q. All of the opinions that you intend to offer at trial are set forth in your report, correct?
  - A. Yes, I hope so.
- Q. Do you agree not to offer any opinions at trial that are not set forth in your report?
  - A. No.
  - Q. Why not?
- A. Because my report is in response to

  Mr. Johnston's report. So I'll follow Mr. Johnston

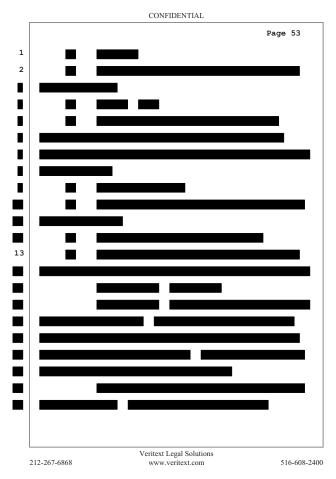
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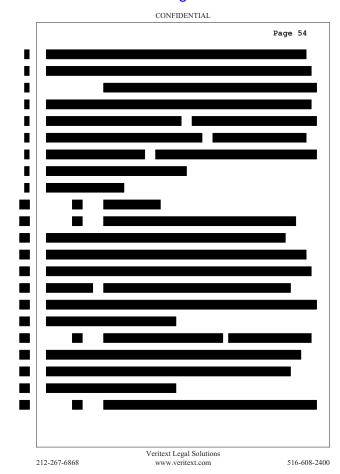
Page 52

at trial maybe. If I follow him at trial, and he testifies to something that wasn't in his report, I'd like a fair opportunity to respond to that. But I'll let counsel decide what fair notice is, and what the boundaries are for my opinions.

- Q. You are aware that Mr. Johnston expressed opinions on the litigation costs that Forest and Mylan saved by settling the Namenda patent litigation, correct?
  - A. Yes
- Q. Your report does not respond to any of those opinions relating to litigation costs, correct?
  - A. Correct
- Q. You're aware that Mr. Johnston expressed opinions relating to the validity of the patent term extension that was granted with respect to the '703 patent, correct?
  - A. Correct.





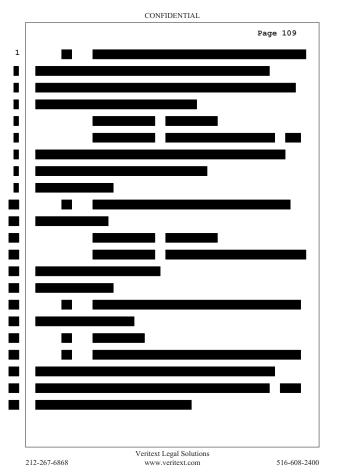


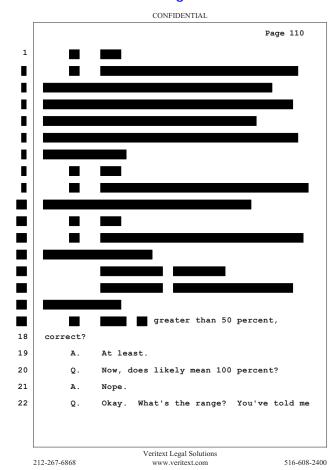
CONFIDENTIAL Page 55 18 Yeah, I'm just trying to get the timeline that you described. It sounded like the post trial 19 20 briefing process is a roughly three-month process, 21 is that correct? 22 No, four-month.

CONFIDENTIAL. Page 56 1 ο. Four-month process. 2 About a month to get the transcripts. Maybe 45 days -- maybe it's three to four months. 3 4 Okay. ο. 5 Α. You have to get the trial transcripts 6 from the court reporter. You have to take a break, 7 and then go about writing your brief, get the 8 associates at the law firm to write the draft of the 9 brief while you take vacation. And the other side 10 needs 30 days to digest that. And then you get 15 days for the associates to draft a reply. 11 Veritext Legal Solutions

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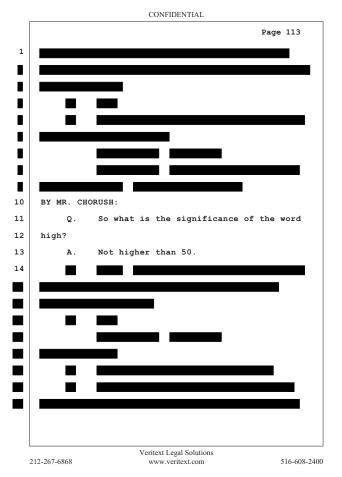
CONFIDENTIAL Page 111 1 that likely means greater than 50 percent, but below 2 what? 3 Just likely. You speak French. I speak Α. 4 German. So when you say likely -- strike that. 22 When you say Forest likely would have

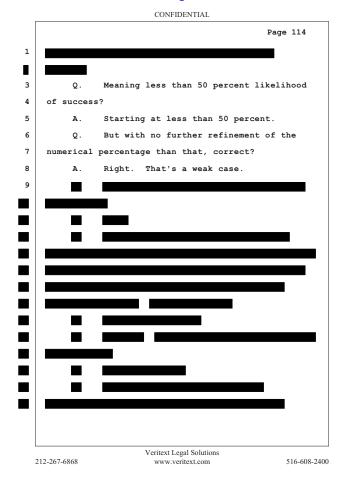
Page 112

prevailed on infringement, do you mean something
between 51 percent and 80 percent?

A. I mean likely. I don't think percentages
are helpful.

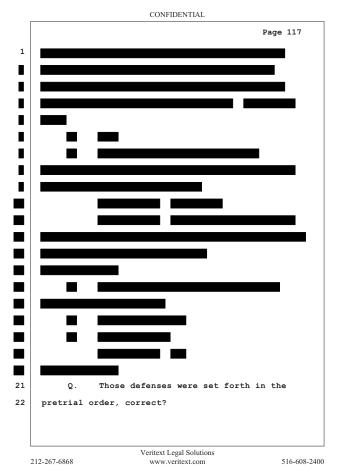
### Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 59 of 171





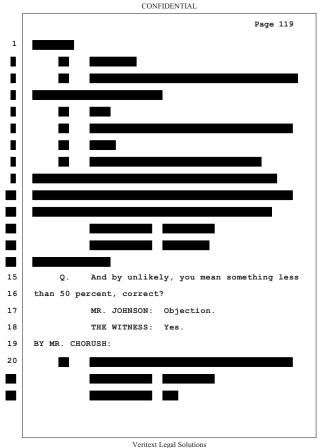
CONFIDENTIAL Page 115 1 3 18 Q. What do you mean by substantially 19 less than 50 percent? 20 Substantially less than 50 percent. Α. 21 Q. Does that mean 40 percent? 22 I don't think numbers are helpful.

CONFIDENTIAL Page 116 1 I understand, but you're using the term 2 substantially, and I'm trying to understand what you mean by that? 3 It's a weak defense. They're not likely 4 5 to prevail on it. 6 15 Q. And by unlikely to prevail, you mean 16 something less than 50 percent correct? 17 18 MR. JOHNSON: Objection. BY MR. CHORUSH: 19 20 Please turn to paragraph 124. ο. 21 A. Right. 22 Veritext Legal Solutions



Page 118 1 But they were listed in the pretrial 2 order. They weren't really advanced in the pretrial 3 order. By advanced meaning moving forward. 4 10 Does that mean something less than 50 11 percent? 12 MR. JOHNSON: Objection. 13 THE WITNESS: Yes. BY MR. CHORUSH: 14 15 Can you be any more specific than that? ο. No, because they didn't really set out 17 their case. It just didn't look like they were even 18 going to pursue it. 19 Veritext Legal Solutions 212-267-6868 516-608-2400 www.veritext.com

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CONFIDENTIAL Page 120 1 9 BY MR. CHORUSH: 10 And by unlikely, you mean something less than 50 percent, correct? 11 12 Yes. 13 MR. JOHNSON: Objection. 14 BY MR. CHORUSH: 15 Q. And you can't be any more specific than 16 that, is that correct? MR. JOHNSON: Objection. 17 18 THE WITNESS: More specific than 19 unlikely. No. BY MR. CHORUSH: 20 21 Or more specific than less than 50 Q. 22 percent?

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Page 121 1 MR. JOHNSON: Objection. THE WITNESS: That's not my opinion. My 2 3 opinion is unlikely. MR. JOHNSON: Russ, let us know when it's 4 time for a break. I think it's been more than an 5 6 hour or so. 7 MR. CHORUSH: Oh, have we been going an 9 MR. JOHNSON: I think, but someone can 10 correct me if I'm wrong. 11 MR. CHORUSH: All right. Let's take a 12 break. 13 VIDEO TECHNICIAN: We are going off the record. The time is 11:21. 14 15 (Recess.) 16 VIDEO TECHNICIAN: We are back on the 17 record at 11:32. (McKelvie Exhibit No. 8 was 18 marked for identification.) 19 20 BY MR. CHORUSH: 21

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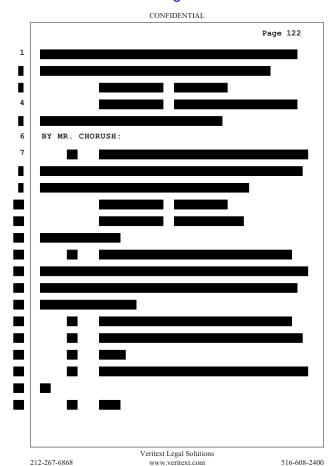
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Let me ask my question again. I'm not sure that you answered it. At the time of the settlement of the Namenda patent litigation, Forest -- strike that.

At the time of the Namenda patent litigation, the trial court had not ruled on the merits of any of Mylan's eight defenses, correct?

MR. JOHNSON: Objection.

THE WITNESS: Correct.

10 BY MR. CHORUSH:

> ο. At the time of the settlement of the Namenda patent litigation, Forest had not requested summary judgment on any of the eight defenses that Mylan had raised, correct?

> > MR. JOHNSON: Objection.

THE WITNESS: I haven't seen any summary judgment motions.

18 BY MR. CHORUSH:

> Forest could have sought summary judgment on any of those eight motions if it believed that any of Mylan's defenses was so weak that Forest was entitled to summary judgment, correct?

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Page 124 1 MR. JOHNSON: Objection. 2 THE WITNESS: I'm not familiar with what Judge Sleet ordered about summary judgment, but I 3 assume they could have filed a motion for summary 4 5 judgment. BY MR. CHORUSH: 7 Mylan only needed to succeed on one of 8 the eight defenses shown on Exhibit 8 in order to prevail in the Namenda patent litigation, correct? 9 10 11 Q. In order to prevail in the patent litigation. Forest had to succeed on all eight of 12 13 the defenses that Mylan had raised, as shown in 14 Exhibit 8, correct? MR. JOHNSON: Objection. 15 16 THE WITNESS: To the extent that Mylan pursued them at trial. 18 BY MR. CHORUSH: 19

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Page 177 1 Q. Do you agree with me that claims that are 2 broadened in re-examination are invalid? 3 I didn't give an opinion on that. Α. What is your understanding of the law? 5 MR. JOHNSON: Objection, outside the 6 scope. 7 THE WITNESS: I prefer not to give 8 opinions on the law. 9 BY MR. CHORUSH: 10 Have you ever seen a case that addressed 11 whether or not claims that are broadened in 12 re-examination are valid? 13 MR. JOHNSON: Same objection. THE WITNESS: I've seen cases where 14 claims are broadened within the two-year period 15 after a patent was issued. I have seen cases, but 17 that's my answer. BY MR. CHORUSH: 18 19 That refers to reissue proceedings, not re-examination proceedings, right? 21 Α. Right. 22 But there was no reissue proceeding in

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Page 178 1 the '703 patent, correct? 2 Correct. 3 Q. There was just a re-examination proceeding, correct? 5 A. Correct. 6 Ο. Have you read the statute relating to re-examination of patents? I'm sure I have. 9 MR. JOHNSON: Objection. 10 BY MR. CHORUSH: 11 ο. Have you ever seen a case that addresses 12 whether a patent owner can obtain claims in 13 re-examination that are broader than the originally issued claims? 14 I've seen cases like that. I'm just not 15 prepared to give an opinion on the broadening 17 18 ο. Do you agree with me that if an 19 independent claim is not infringed, that dependent claims cannot be infringed either? MR. JOHNSON: Objection. 21 22 THE WITNESS: That's correct.

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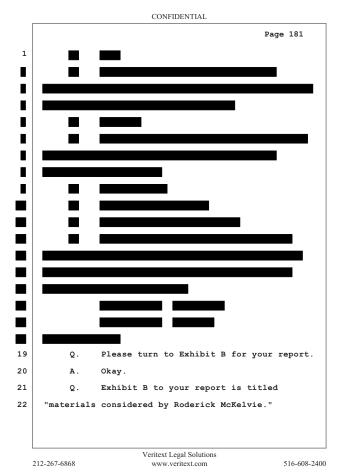
BY MR. CHORUSH:

12 13

And in the originally issued '703 patent, there was only one independent claim, correct? I don't recall. MR. JOHNSON: Objection. BY MR. CHORUSH: Let's take a look. MR. JOHNSON: We should break for lunch at some point soon, I think. MR. CHORUSH: Okay. Let's break for lunch, then. VIDEO TECHNICIAN: Going off the record. The time is 12:39. (Whereupon, at 12:39, a luncheon recess was taken.) Veritext Legal Solutions

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Page 180 1 AFTERNOON SESSION 2 (1:39 p.m.) 3 Whereupon, RODERICK McKELVIE. 4 5 was called for continued examination, and having been previously duly sworn was examined and testified further as follows: EXAMINATION BY COUNSEL FOR PLAINTIFF CONTINUED 8 9 VIDEO TECHNICIAN: We are back on the 10 record at 13:39. 11 BY MR CHORUSH: 12



Page 182 1 Correct? 2 Α. Correct. 3 And you break the materials considered Q. into several different categories, correct? 5 6 11 And you list a number of the pleadings by ECF number in that portion of Exhibit B, correct? 12 13 Α. 14 ο. What does ECF refer to? 15 I assume it's a docket item number. Α. Okay. And you place those in order of 17 the docket control numbers, starting with number 1 18 up to number 498, correct? 19 Yes. Veritext Legal Solutions 212-267-6868 516-608-2400 www.veritext.com

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Page 183 1 2 5 MR. JOHNSON: Counsel, I would note that 7 it appears that what's appended here to Judge McKelvie's report is his original Exhibit B, not the 8 9 revised Exhibit B that we've served on you. I'm 10 just noting that for the record. MR. CHORUSH: Okay. Just so we'll know, 11 12 because I printed this out beforehand, does the 13 revised Exhibit B change Exhibit B with respect to 14 either Mylan's answering claim construction brief or the -- Mylan's objection to the report and 15 16 recommendation on claim construction. 17 MR. JOHNSON: No, I don't believe it did. 18 I think we have copies of that if it would help you, 19 but --MR. CHORUSH: If you'd like to introduce 20 the amended Exhibit B at some point, that's fine. 22 This is the copy that I have.

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CONFIDENTIAL Page 184 MR. JOHNSON: Okay. 1 2 BY MR. CHORUSH: 3 

# EXHIBIT 315

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Page 1
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             IN THE UNITED STATES DISTRICT COURT
                 SOUTHERN DISTRICT OF NEW YORK
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     IN RE: NAMENDA DIRECT
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                              | No: 15-cv-7488-CM(JF)
     PURCHASER ANTITRUST
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     LITIGATION
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       Videotaped Deposition of David L. Rosen, J.D.
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                       Washington, D.C.
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     Job No. 2732014
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    Reported by: Laurie Donovan, RPR, CRR, CSR
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DAVID L. ROSEN, J.D.

Page 57 BY MR. ENGER: 6 0 Mr. Rosen, do you realize you're still under oath? 8 Α Yes, I do. 9 Is there any testimony from earlier this Q 10 morning you need to correct or amend at this time? 11 Not that I'm aware of. 19 Mr. Rosen, you've just been handed Exhibit 3, which is 35 U.S.C. Section 282. 20 21 Have you ever seen this statute before? 22 23 This is the statute for patent defenses. 24 Do you see that from the title? Veritext Legal Solutions

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DAVID L. ROSEN, J.D.

Page 58 1 Q You've never read this statute? 2 Α No. 3 You wouldn't consider yourself to be an expert on this statute? 5 Α 6 Direct your attention to the second page. See right about here where it says "Invalidity of the extension"? 8 9 Do you see that? Yes, I do. 10 11 Let me read it to you. 12 This statute, 35 U.S.C. Section 282, 13 states that "Invalidity of the extension of a patent term or any portion thereof under Section 14 15 154(b) or 156 of this Title because of the material failure by the applicant for the 16 17 extension, or by the Director, to comply with the 18 requirements of such section shall be a defense in 19 any action involving the infringement of a patent during the period of the extension of its term and 20 21 shall be pleaded." 22 Do you see that? 23 24 So you would agree that if you violate the portion of the statute where an applicant for Veritext Legal Solutions 212-267-6868 516-608-2400

### DAVID L. ROSEN, J.D.

1 the extension or the Director does a material 2 failure to comply with the requirements, then the 3 patent term extension is invalid? 4 MR. MAJCHRZAK: Objection. Calls 5 for a legal conclusion. Outside the scope of 6 Mr. Rosen's report. 7 THE WITNESS: You know, I can just 8 read the words, but I can't draw any 9 conclusions from that. 10 BY MR. ENGER: 11 Do you see the word "material failure" 12 in that portion of the statute? 13 14 What is a "material failure" under 35 U.S.C. Section 282? 15 MR. MAJCHRZAK: Objection. Calls 16 17 for a legal conclusion. Outside the scope. THE WITNESS: I'm not able to opine 18 19 on that. BY MR. ENGER: 20 21 Are you aware of any case law that interprets Section 282's "material failure" 22 23 language? 24 MR. MAJCHRZAK: Same objection. THE WITNESS: It's outside the

	DAVID L. ROSEN, J.D.
	Page 60
1	scope. I'm not able to opine on that.
2	BY MR. ENGER:
3	Q My question was: Are you aware yes
4	or no of any case law that interprets Section
5	282's "material failure" language?
6	A No.
7	Q Per the statute, whose material failure
8	triggers the defense?
9	MR. MAJCHRZAK: Objection. Calls
10	for a legal conclusion. Outside the scope.
11	THE WITNESS: Just the plain
12	reading of the statute, the language says "by
13	the applicant for the extension or by the
14	Director."
15	BY MR. ENGER:
16	Q Does the applicant file the extension
17	with the Patent Office?
18	A I'm not 100 percent sure of that.
19	Q Whenever it says "the Director," does
20	that refer to the Director of the Patent Office?
21	A I'm not, I'm not going to opine on that
22	either.
23	Q Are you aware of any other directors
24	relating to patent term extension?
25	A No.

DAVID L. ROSEN, J.D.

Page 61 1 Would you agree that 35 U.S.C. Section 2 282 is a statute about the Patent Office? 3 MR. MAJCHRZAK: Objection. Calls 4 for a legal conclusion. 5 THE WITNESS: It's a, it's a statute -- it's a -- appears to be a statute 6 on "remedies for infringement of patent and other actions," by its title. 8 9 (Exhibit 4 was marked for 10 identification.) 11 BY MR. ENGER: 12 Q I'm going to hand you what's been marked 13 as Exhibit 4. 14 Mr. Rosen, Exhibit 4 is 35 U.S.C. 15 Section 156. You said this was one of the things you reviewed in preparation for your deposition 16 17 18 A Yes. 19 And you've seen this before? 20 А 21 Have you read it from cover to cover? 22 I have read it. I don't know if I've 23 read it cover to cover, but I have read it. 24 How many times have you read it? 0 I don't know.

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		ŀ	age 62
1	Q	More than five?	
2	A	Possibly.	
3	Q	More than ten?	
4	A	Probably not.	
5	Q	Would you consider yourself to h	oe an
6	expert on	this statute?	
7	A	No.	
8	Q	Let me direct you to the second	page to
9	Section (d	1)(1).	
10		Do you see that? It's kind of a	at the
11	top right	of the second column.	
12	A	Yes.	
13	Q	So 35 U.S.C. Section 156(d)(1)	states
14	that "To o	btain an extension of the term of	of a
15	patent und	ler this section, the owner of re	ecord of
16	the patent	or its agent shall submit an	
17	application	on to the Director," right?	
18	A	That's what the language says, y	yes.
19	Q	And then two sentences later, the	ne
20	statute li	sts the contents of the applicat	tion;
21	fair?		
22	A	I'm not exactly following you.	
23	Q	See at the end of this paragraph	n where
24	it says "t	the application shall contain"?	
25	A	Yes.	
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	Page 63
1	Q And it has a list of subsumed
2	paragraphs, A, B, C, et cetera?
3	A Yes.
4	Q So this statute lists what the contents
5	of the application "shall contain"; fair?
6	A Yes.
7	Q Does the application have to have each
8	of the five things labeled A through E in the
9	statute?
10	MR. MAJCHRZAK: Objection. Calls
11	for a legal conclusion.
12	THE WITNESS: The language of the
13	word says "shall contain," so generally,
14	yeah, that is a it's language that says
15	that an application "shall contain" things.
16	BY MR. ENGER:
17	Q Must contain.
18	A It says "shall contain."
19	Q Is there any difference in your mind
20	between "shall contain" and "must contain"?
21	A No.
22	Q Is it acceptable for an application a
23	patent term extension application, I should say
24	to contain only two of those five things?
25	MR. MAJCHRZAK: Objection.

	DAVID L. ROSEN, J.D.
	Page 64
1	THE WITNESS: I'm not, I'm not
2	capable of rendering an opinion on that
3	situation.
4	BY MR. ENGER:
5	Q Is it acceptable for a patent term
6	extension application to contain only four out of
7	those five things?
8	MR. MAJCHRZAK: Objection.
9	THE WITNESS: I'm not able to
10	render an opinion with respect to that.
11	BY MR. ENGER:
12	Q Is it a material failure under Section
13	282 if a patent term extension application does
14	not contain each of the five things enumerated in
15	Section 156(d)(1)?
16	MR. MAJCHRZAK: Objection.
17	THE WITNESS: I'm not able to
18	render an opinion on that situation.
19	BY MR. ENGER:
20	Q Do you see (d)(1)(C)?
21	A I see that.
22	Q Do you see that one of the things that
23	the application shall contain is "information to
24	enable the Director to determine under subsections
25	(a) and (b) the eligibility of a patent for

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Page 65

extension and the rights that will be derived from the extension"?

Do you see that?

Yes.

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Per this statute, who is it that determines the eligibility of a patent for extension and the rights that will be derived from the extension?

MR. MAJCHRZAK: Objection.

THE WITNESS: Yeah, I'm not able to

render an opinion with respect to that.

BY MR. ENGER:

- Can you not see where it says that the Q Director is who must be enabled to determine the eligibility of a patent for extension?
- That's the language that appears to be in the statute, yes.
- Do you have any reason to doubt that it 0 is not the Director who is, in fact -- determines whether a patent is eligible for -- an application is eligible for a patent term extension?
- Well, it talks about "information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture."

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that to come to that conclusion. BY MR. ENGER:

Let's direct your attention to the next subsection, specifically 156(d)(1)(D).

Are you there?

- Α
- Per this statute, does the application also have to include "a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities"?
  - Yes, I see that.
- What type of information is submitted as part of the "brief description of the activities undertaken by the applicant during the applicable regulatory review period"?
- А That's a chronology of events relative to both the IND and the NDA.
  - Anything else?
- That's -- a brief description of the activities, that's correct.
- Does the chronology have to -- that's submitted have to cover the entire review period or just a part of the review period?

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Do you see what the information that has to enable the Director and Secretary of Health and Human Services or the Secretary of Agriculture, uh, that information has to determine the period of extension under Subsection (d), right? Under Subsection (a)?

- That appears to be the language of the statute, ves.
- So the Director is who determines the eligibility of the patent for extension and the rights that will be derived, and the Director and the Secretary of Health and Human Services or the Secretary of Agriculture determines the period of extension under Subsection (g)?
- That appears to be the plain language of the statute.
- What information must be included in the application to enable the Director to determine the eligibility of a patent for extension and the rights that will be derived from the extension?
  - I'm not able to answer that question.
- Do you believe it's the information specified in 37 C.F.R. Section 1.740?

MR. MAJCHRZAK: Objection.

THE WITNESS: I haven't reviewed

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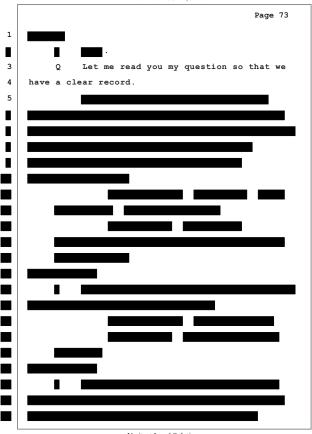
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- It says "during the applicable regulatory review period and significant dates."
- So does that mean that the chronology that's submitted has to be, just cover part of the review period or the entirety of the review period?
- "A brief description of activities during the applicable regulatory review period."
- And I'm asking if that means a portion of the applicable regulatory review period or the entirety of the applicable regulatory review period.
- It says "during the applicable regulatory review period," and so I would -- you know, not being -- having reviewed these for other people, we have tried to make those as, you know, as complete as possible to make a regulatory determination
- You would never advise a client to submit a chronology of events that just covers a portion of the applicable regulatory review period, would you?
  - I don't believe I would do that, no.



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Page 74 1 20 0 I'm handing you what's been marked as 21 Exhibit 5. 22 Mr. Rosen, Exhibit 5 is 37 C.F.R. 23 Section 1.740. Have you ever seen this regulation 24 before? 25 А No.

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- You can see from the title, this is the regulation governing the formal requirements of a patent term extension application, correct?
- From the language of the C.F.R., that appears to be correct, yes.
- Q You've never read this regulation, correct?
  - Α That's correct.
- You wouldn't consider yourself an expert Q on this regulation?
  - That is correct.
- Does this regulation require -- and I'm looking in the first paragraph -- that "a formal application for the extension of patent term must include" a number of things, enumerated 1 through 15?

MR. MAJCHRZAK: Objection. Legal conclusion. Outside the scope.

THE WITNESS: I've never read that,

but just let me -- is there 15 of these

21 things?

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That appears to be the case, just from looking at this document.

BY MR. ENGER:

So per this regulation, does an

	DAVID L. ROSEN, J.D.
	Page 76
1	application for patent term extension have to
2	include each of these 15 things?
3	MR. MAJCHRZAK: Same objection.
4	THE WITNESS: I can't draw a
5	conclusion. All I can do is just read the
6	plain language of the C.F.R., and it says
7	"must."
8	BY MR. ENGER:
9	Q You've read a lot of government
L O	regulations in your practice, correct?
L1	A Correct.
L2	Q And you don't know any other way to
L3	interpret this other than that the patent term
L 4	extension application must include the 15 things
L 5	enumerated in Section 1.740?
L 6	MR. MAJCHRZAK: Objection. Legal
L 7	conclusion. Outside the scope.
L 8	THE WITNESS: Again, having read
L 9	numerous other C.F.R. provisions, I'm not
20	you know, I have not read this one, but yeah,
21	I'm just looking at the language here, and it
22	says "must include."
23	BY MR. ENGER:
24	Q Is it a material failure not to include
25	each of the 15 things enumerated in 37 C.F.R.

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Section 1.740?

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MR. MAJCHRZAK: Same objection. THE WITNESS: I'm not in a position to offer an opinion on that.

BY MR. ENGER:

- If Mr. Johnston offers an opinion that it is a material failure to not include each of the items in 37 C.F.R. Section 1.740, you're in no position to rebut that; fair?
  - I'm not in a position to rebut that.
- Direct your attention to the second page, please. Do you see Section 1.740(a)(10)? It's about in the middle of the first column.
  - Yes
- This says that one of the things that the patent term extension application must contain is "a statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period."

Do you see that?

- Yes, I see that.
- And for patents that claim a human drug,

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such as the '703 patent, the information that must be included is, A, the effective date of the investigational new drug (IND) application and the IND number; B, the date on which a new drug application (NDA) was initially submitted and the NDA number; and C, the date on which the NDA was approved, correct? Yes.

When completing this portion of the Q patent term extension application, how does one determine, A, "the effective date of the investigational new drug (IND) application"?

There's correspondence with FDA.



So who determines the effective date of the IND application?

It's set forth in the letter from FDA to the applicant, the IND applicant.

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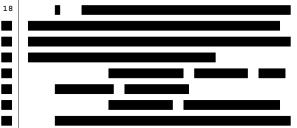
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- And what criteria does the FDA use to write that letter and set that date?
- It's the date that the application is received, and then the IND becomes effective 30 days from the day of receipt.
  - Q So it's pretty ministerial?
- You submit an IND. 30 days later -- I'm sorry. It's ministerial in the fact that you submit an IND, it's received, and 30 days later, that's the effective date?
- A Unless FDA says that you're on clinical hold.
  - Could you elaborate, please?
- A clinical hold is something where the, the -- there's a substantial risk of harm to patients, and you can't start a study as proposed under the IND until you address those situations and FDA allows you to proceed with the investigations.
- So if the FDA puts your IND on clinical hold, then the IND's effective date is not 30 days from its initial submission but some other date?
  - Α That's correct.
  - And what's that other date?

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- Α Whenever FDA says that you can start the study.
- Back to Exhibit 5, please, the bottom of Q page 163.
  - А
  - Q Do vou see 37 C.F.R. Section
- 1.740(a)(11)?
- Α
- Another of the things that the patent application must contain is, 11, "a brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities," correct?
- I see that, yes.



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If the applicant believed that the applicable regulatory review period was one period, was one length -- are you with me?

- I'm with you.
- Would you ever advise that client to only submit a description of the significant activities that occurred during a portion of the applicable regulatory review period as the client understood it at that time?
- No. I would want them to provide information, but in this situation they disclosed -- when the original IND was submitted, they disclosed the activities under the IND, they disclosed when the IND was inactivated, they also disclosed when the IND was reactivated, and they also provided information on the foreign studies that were conducted during the time of inactivation.
- So no, you would never advise a client to only submit a description of the significant

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conclusion. Speculation.

THE WITNESS: It's to help determine the regulatory review period. BY MR. ENGER:

- How does the applicant determine the length of the extension that's claimed?
- They count the number of days in the IND phase or the testing phase and the number of days in the review phase, and they -- there's a, a formula to calculate the regulatory review period.
- And that formula takes into account the number of days during that review period whenever they were not diligent?
- I didn't say that they were -- you know, there's a calculation on what they determine to be the regulatory review period. I don't believe that there's, uh, that they make a determination at that time whether or not they're not diligent or not or what -- or they would say that -- you know. I don't think there's a diligence calculation figured into that at that point.
- You're not aware of patent term extension applications here in this section where they explicitly state the number of days whenever they were not diligent?

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activities that occurred during a portion of the applicable regulatory review period as the client understood it at that time; fair?

MR. MAJCHRZAK: Objection.

THE WITNESS: I think I answered

Page 86

6 the question.

BY MR. ENGER:

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Let me direct your attention to Exhibit 5, the twelfth requirement for a patent term extension application.

Do you see it?

- 12 Yes. Α
  - Here it says in the regulation that 0 another of the things that the patent term extension application must contain is, 12, "a statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined, " correct?
  - That's what the -- that's what that provision reads, yes.
  - Why is it important to include that information in the application?

MR. MAJCHRZAK: Objection. Legal

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- Oh, there were, there were some inactivations and things of that sort and, you know, what they were claiming for patent extensions in this situation. The applicant decided that they determined that the extension was calculated under certain -- you know, at a later date when the IND was reactivated as opposed to when the IND was originally submitted.
- So let's take a step back. Let's divorce from the facts of this case. I just want to understand your general understanding of the statutes and what's the requirements of the patent term extension application, okay?
- In general, the applicant, as part of a patent term extension application, is required to affirmatively state, under the section where it determines how the requested patent term extension is calculated, an affirmative statement about the number of days in which it was not diligent, right?
- No. It's, it states when the IND was active, when it become -- when it became in effect, and then it became when it was -- uh. during the inactivation period, they could at

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least note that, and just because it was inactive doesn't mean that, doesn't mean that somebody was not diligent in the course of the testing phase.

- Q In general, not on the facts of this case, you're telling me that there's no requirement that an applicant affirmatively state the number of days in which it was diligent and not diligent?
- A I would want to go back and review that one more time, but I don't know if there's a, there's something that is a specific statement that says that you have to state that you were not diligent. You could say that there was no activity during this particular time frame, and somebody else would draw the conclusion as to whether or not there was diligence or not diligence during that time frame.
- Q You've never prepared a patent term extension application?
  - A I didn't say that.
- Q Have you?

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- A I have participated in the preparation of patent term extension applications.
- Q Have you participated in the drafting of a patent term extension application involving this

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Page 90 1 Section (12), which is the statement that the patent is eligible for the extension, a statement 2 as to the length of the extension claim, 3 including, importantly, how the length of the extension was determined? I did not, never -- I never prepared that particular statement. 8 So it's entirely possible that you are 9 required to make an affirmative statement in a patent term extension application as to the number 10 11 of days which you were not diligent; you don't 12 know? 13 I can't draw a conclusion to that Α 14 effect. 15 Because you just don't know? 16 That's correct. Α 17 I want to direct your attention to the 18 thirteenth requirement for a patent term extension 19 application. 20 Do vou see that? 21 Yes. 22 Another of the things that the patent 23 term extension application must contain is, 13, 24 "a statement that applicant acknowledges a duty to disclose to the Director of the United States

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Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought," correct?

- A That's what that statement says.
- Q This duty; is it set forth in 37 C.F.R. Section 1.765?
- ${\tt A} \qquad {\tt I \ can't \ say.} \quad {\tt I \ have \ not \ read \ that}$  section.
- Q Do you know why the government requires patent term extension applicants to acknowledge their duty to disclose material information?

MR. MAJCHRZAK: Objection.

Speculation.

THE WITNESS: Not particularly, no. BY MR. ENGER:

18 Q That never came up while you were at the 19 FDA?

- A No.
- Q And it's never come up in your practice?
- A Not this particular situation, because I have not been involved in the preparation of those statements
  - Q Why is it important that the Patent

DAVID L. ROSEN, J.D. Page 92 1 Office have all the material information before it 2 when determining patent term extension eligibility? 3 MR. MAJCHRZAK: Objection. 5 Speculation. Outside the scope. 6 THE WITNESS: I'm not a patent officer. I don't practice in front of the TIS PTO 8 9 10 If the Patent Office didn't have all the 11 material information before it, it might make a 12 wrong determination; fair? 13 MR. MAJCHRZAK: Objection. 14 Speculation. Outside the scope. 15 THE WITNESS: I can't say, but it 16 makes some sense that they could come to a different conclusion, perhaps. 18 BY MR ENGER . 19 That makes a lot of sense, doesn't it? MR. MAJCHRZAK: Objection. 20 21 THE WITNESS: Not necessarily, but 22 it just makes sense. 24 It makes, it makes sense that the Patent

Office should have all the material information

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Page 97 Another person who owes the Patent and

Trademark Office a duty of candor and good faith is "each attorney or agent who represents the patent owner"; fair?

MR. MAJCHRZAK: Objection. Legal conclusion. Outside the scope.

THE WITNESS: That's what the, the language of the C.F.R. says.

BY MR. ENGER:

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And "every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding" also owes that same duty of candor and good faith, right?

> MR. MAJCHRZAK: Same objection. THE WITNESS: That's what the

C.F.R. says. 18

BY MR ENGER .

0 Do you see the second sentence of Section (a)?

Starting with?

"All such individuals."

I see that sentence, the beginning of that sentence, yes.

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Page 98 1 Why don't you read that sentence in your 2 head, and then I want to ask you a few guestions 3 (Witness peruses document.) 5 THE WITNESS: Okay. 6 BY MR. ENGER: 7 Per this regulation, what, what steps are individuals who are aware of material 8 9 information adverse to a determination of entitlement to the patent term extension sought 10 11 required to do? 12 MR. MAJCHRZAK: Objection. Legal 13 conclusion. Outside the scope. THE WITNESS: I'm only reading from 14 15 the C.F.R. that the -- if they become aware 16 -- "if they are aware, or become aware, of 17 material information adverse to a 18 determination of entitlement . . . which has 19 not been previously made of record in the 20 patent term extension proceeding must bring 21 [that] to the attention of the Office or the 22 Secretary . . . as soon as it is practical to

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likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding."

BY MR. ENGER:

So individuals involved in a patent term application -- patent term extension application have to disclose material information to the Patent Office; fair?

MR. MAJCHRZAK: Objection. Legal conclusion. Outside the scope.

THE WITNESS: This is not an area that I practice in, so it's very hard for me to opine on any of this information.

BY MR. ENGER:

What if, after a patent term extension application is submitted, one of these individuals who owes the duty of candor and good faith becomes aware of material information? What are they required to do?

MR. MAJCHRZAK: Objection. Legal conclusion. Outside the scope. THE WITNESS: I can only read it's

material information "where there is a substantial likelihood that the Office or the DAVID L. ROSEN, J.D.

do so after the individual becomes aware of

the information," and "Information is

material where there is a substantial

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Secretary would consider it important in determinations," and the patent determination would be to bring it to the Secretary as soon as possible.

BY MR. ENGER:

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So this duty to disclose material information exists before you file the application and also continues to exist after you file the application; fair?

MR. MAJCHRZAK: Objection.

THE WITNESS: Again, I'm not an expert in this area, and it's very hard for me to render any conclusions other than just to read the plain language of the statute -of the regulations.

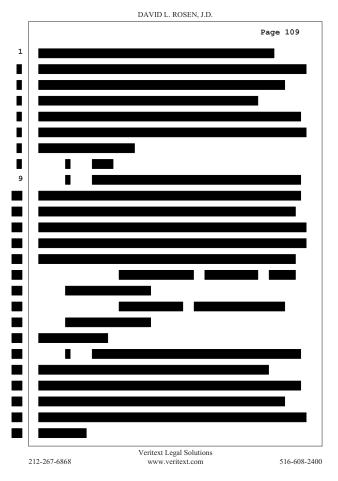
BY MR ENGER:

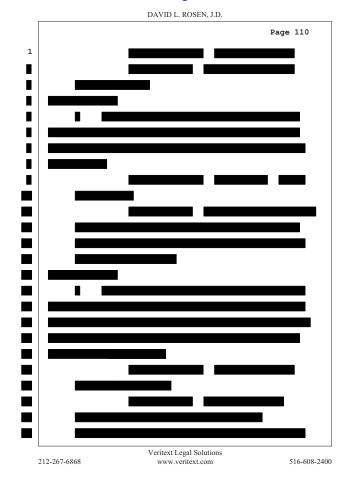
And when you read the plain language, you would agree that the duty of candor and duty to disclose material information exists both before the application is filed and after the application is filed; fair?

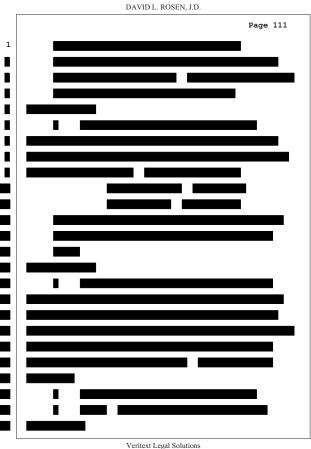
MR. MAJCHRZAK: Objection.

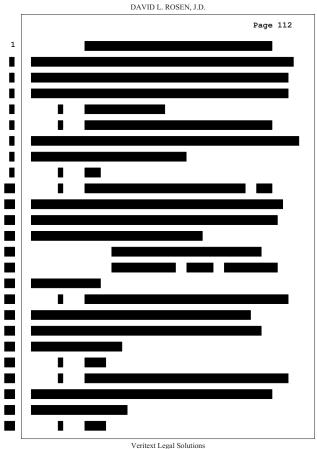
THE WITNESS: It appears that to be the case.

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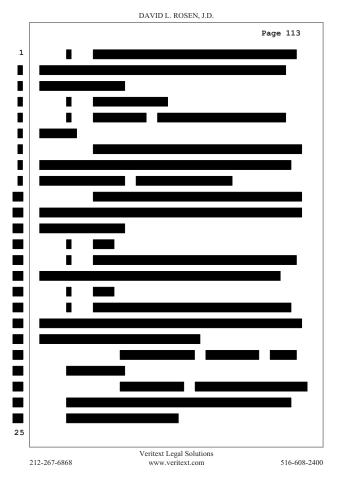
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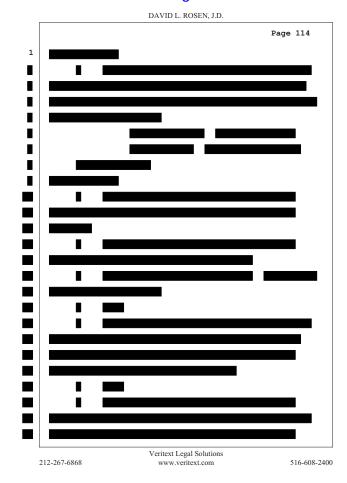
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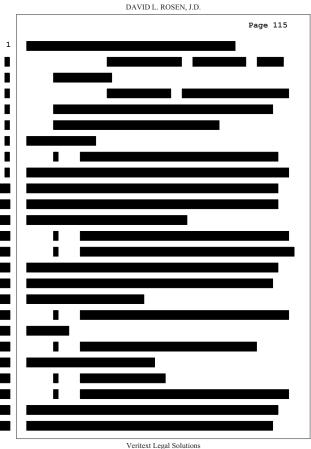
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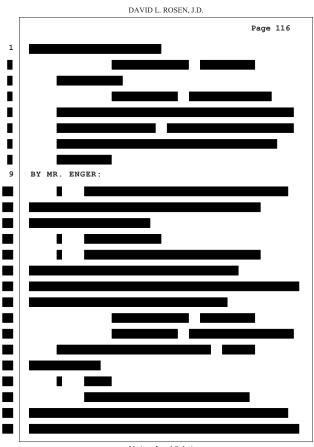
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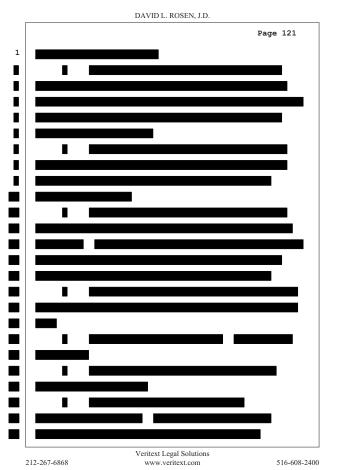
### Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 75 of 171

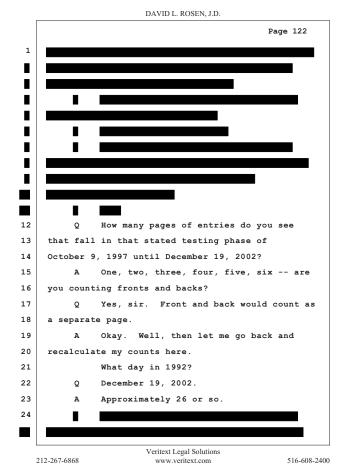


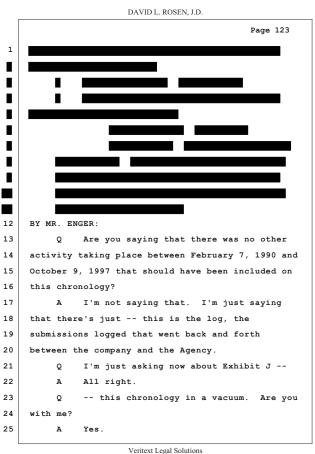


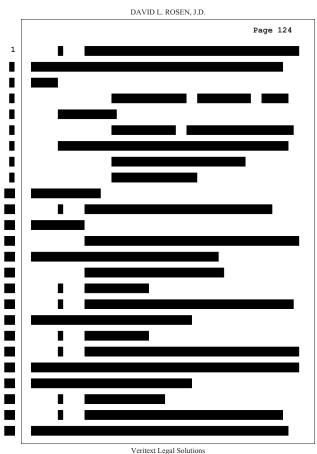




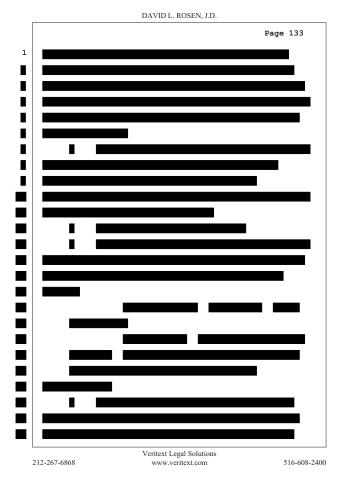


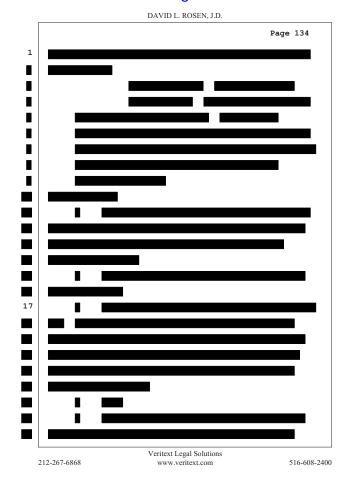


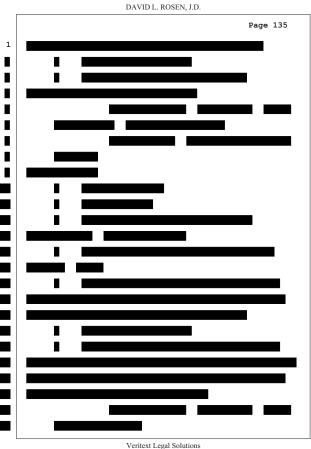


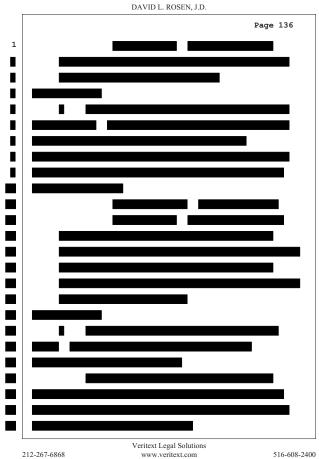


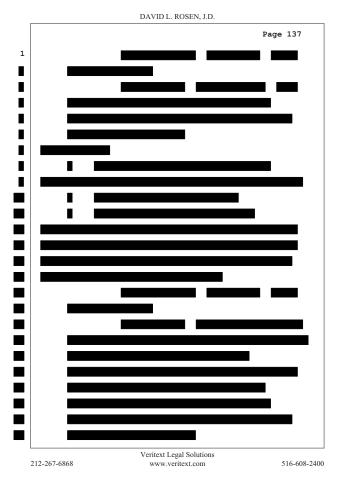
### Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 77 of 171

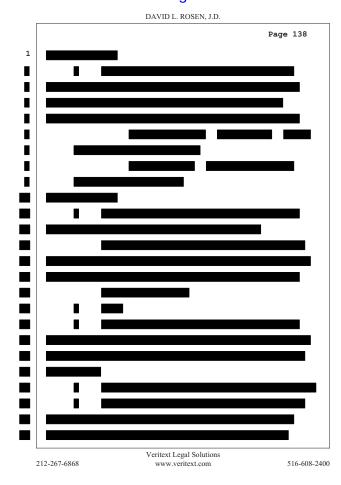


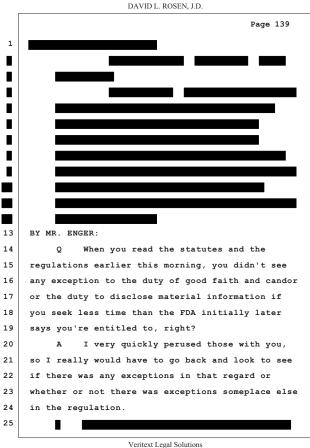


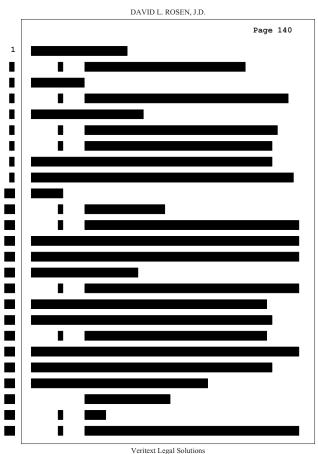












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- Really the only people that would know if they were diligent during the entirety of the study is the study's participants?
- It would be the applicant as well as the principal investigators, as well as the actual patients that were included in the trial, but again there's a lot of activities that are supportive with respect to review and analysis of data, data entry, data quality situations that would be a part of the conduct of any clinical trial. So just not -- just necessarily not seeing patients on a given day would not mean that a company was not being diligent in the conduct of a clinical trial.
- Let's look at the last column of this chart. What information is indicated that would be included in that last column?

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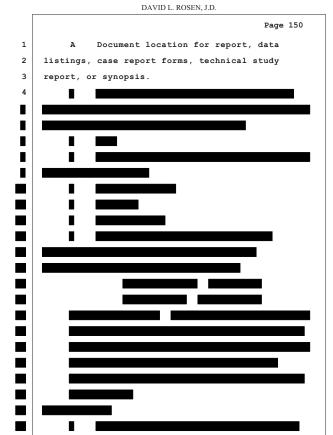
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- What do you mean by the "regulatory review period determination"?
- That's the -- it's the information that we've talked about today with respect to the testing phase and the review phase, the applications.
- Q This statute only permits the FDA to consult its records and experts to determine the length of the product's regulatory review period, right?
  - I believe so, yes.

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Page 152 1 It doesn't authorize the FDA to consult 2 its records or experts to verify the diligence of 3 a, of an applicant during a patent term extension? 4 MR. MAJCHRZAK: Objection. 5 BY MR. ENGER: 6 Q Right? 7 Α I don't believe it does. 8 In the next sentence, you cite 21 C.F.R. 9 Section 60.36(a). 10 Do you see that? 11 A 12 And you cite it for the proposition that 13 the FDA consider -- can consider the "applicant's 14 actions" to determine whether it was diligent? 15 Α Yes. 16 0 Does that regulation -- when is that 17 regulation considered? 18 Α In looking at the entire regulatory 19 review period. 20 Isn't that regulation actually under 21 Subpart D relating to due diligence petitions? MR. MAJCHRZAK: Objection. 22 23 THE WITNESS: I would have to 24 review that in its entirety and look at that portion of the regulations. I don't know it

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Page 153 1 offhand. BY MR. ENGER: 2 3 Let me represent to you that this regulation is under Subpart D relating to due 4 diligence petitions. 6 Are you with me? No. I would have to read it. I would 7 like to read it for myself. 8 9 (Exhibit 10 was marked for 10 identification.) 11 BY MR. ENGER: 12 I've just handed you what's been marked 0 13 as Exhibit 10. This is 21 C.F.R. 60.36. 14 Correct. 15 Do you see -- I guess it's a little 16 difficult. Do you see that Section 60.40 17 corresponds to Subpart E, due diligence hearings? Yes. 18 19 So the regulations under Subpart E only apply if a due diligence hearing occurs, right? 20 21 MR. MAJCHRZAK: Objection. Legal 22 conclusion. 23 THE WITNESS: That's under "Request 24 For Hearing." It appears that to be the

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case, yes, yes.

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Page 154 1 BY MR. ENGER: 2 0 And I apologize that this Exhibit 10 3 doesn't include subsequent regulations, but can't you tell that Section 60.36 is part of Subpart D? I would presume that would be the case, 6 yes. 7 And do you know that Subpart D corresponds to due diligence petitions? 8 9 I will take your word for that. 10 So 60.36 under Section, Subpart D Q 11 related to due diligence petitions only comes into 12 effect if somebody actually files a due diligence 13 petition, right? MR. MAJCHRZAK: Objection. Legal 14 15 conclusion. THE WITNESS: I am not ready to 16 17 opine on this without further evaluation and 18 study. 19 BY MR. ENGER: 20 0 That makes sense, though, what I'm 21 saying, right? 22 It may make sense. 23 You know that no one filed a due 24 diligence petition in the Namenda patent term extension, right?

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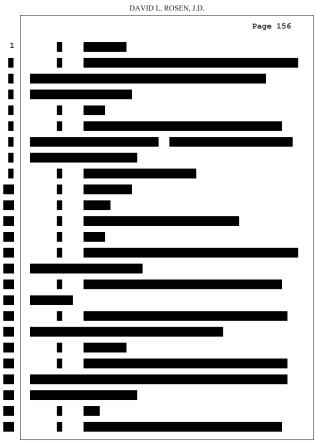
- A I believe that to be the case.
- $\,$  Q  $\,$  So 60.36 doesn't really have any applicability to the Namenda patent term extension application, does it?

 $\label{eq:majchrzak:} {\tt MR.\ Majchrzak:} \quad {\tt Objection.} \quad {\tt Legal}$  conclusion.

THE WITNESS: Although FDA may evaluate that. I mean they, they can't divorce themselves from looking at these types of standards and making these types, in any of the determinations.

BY MR. ENGER:

- Q Are you aware of any statute or regulation that specifically authorizes the FDA to consider all of its files and not just the things in the patent term extension application to determine due diligence?
  - A I'm not aware of that.



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# EXHIBIT 318

	Page 331
1	** HIGHLY CONFIDENTIAL **
2	UNITED STATES DISTRICT COURT
3	SOUTHERN DISTRICT OF NEW YORK
4	Civil Action No. 1:15-cv-07488-CM
5	x
6	
	IN RE NAMENDA DIRECT PURCHASER
7	ANTITRUST LITIGATION
8	
9	x
	November 7, 2017
10	9:02 a.m.
11	
12	
13	Continued Videotaped Deposition of
L 4	FOREST LABORATORIES, LLC; ACTAVIS, PLC;
15	FOREST LABORATORIES, INC.; and FOREST
16	LABORATORIES HOLDINGS LTD., by CHARLES
17	RYAN, Ph.D., taken by Plaintiffs, pursuant
18	to Notice, held at the offices of White &
19	Case LLP, 1221 Avenue of the Americas, New
2 0	York, New York, before Todd DeSimone, a
21	Registered Professional Reporter and Notary
22	Public of the State of New York.
23	
2 4	
25	

Page 341 1 17 18 document prepared? 19 I don't believe so. I'm not sure what you mean by that. 20

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something.

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to begin with. I'm sorry to interrupt.

to talk about different versions or

Maybe we cn break it down if you are going

MR. TOTO: I mean, there is two

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Page 342 1 MR. OPPER: Right. 2 Dr. Ryan, you are also an 3 attorney; is that correct? 4 5 And what is your understanding 6 of what a Rule 30(b)(6) witness is? 7 So a 30(b)(6) witness is an 8 individual who is testifying on behalf of 9 the corporate entity, in this case Forest Laboratories, and you give a 30(b)(6) 10 11 notice to someone when you are not giving a 12 name, but you are giving a topic and you 13 are saying please bring somebody forward 14 who can testify on behalf of, in this case, 15 the entity for a particular subject. Okay. And today you are 16 17 testifying on behalf of Forest Labs; is 18 that correct? 19 Α. Right. What did you do in preparation 20 ο. 21 for today's deposition? 22 I met with counsel. Α. 23 By "counsel"? 24 Α. From White & Case. 25 Mr. Toto and --

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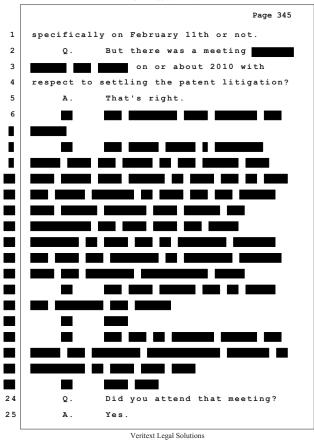
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	HIGHLY CONFIDENTIAL
	Page 343
1	A. Mr. Johnson.
2	Q Mr. Johnson?
3	A. Uh-huh.
4	Q. Did you speak with Eric Agovino
5	about this document?
6	A. Yes.
7	Q. When did you speak with him?
8	A. Yesterday.
9	Q. Was this a face-to-face
10	meeting?
11	A. No. He lives in California, so
12	it was by phone.
13	Q. Did you speak with David
14	Solomon about this let me withdraw that
15	and just ask you, who did you speak with in
16	preparation for today's deposition other
17	than Mr. Agovino and counsel you've already
18	identified?
19	A. Those are the three individuals
20	I spoke with.
21	Q. So you didn't speak to David
22	Solomon, correct?
23	A. I did not speak to David
2 4	Solomon.
25	Q. You did not speak to Rachel

		HIGHLY CONFIDENTIAL
		Page 344
1	Mears?	
2	Α.	No.
3	Q.	You did not speak to Herschel
4	Weinstein?	
5	Α.	No.
6	Q.	You didn't speak to any of
7	Forest's out	tside counsel?
8	Α.	That's correct.
9		MR. TOTO: Well, except the
10	ones mention	ned I guess.
11		MR. OPPER: Yes.
12		
20	Q .	And when was that meeting?
21	Α.	That meeting would have been in
22	February of	2010.
23	Q .	Was there a meeting on February
24	11th, 2010?	
25	Α.	I don't know if it was
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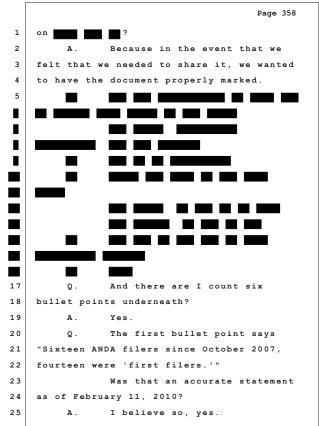
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Page 357 1 3 Dr. Ryan, in your role as an attorney, you are a litigator; is that 4 5 correct? 6 Α. 7 ο. And isn't your understanding 8 that FRE 408 has to do with settlement 9 negotiations between a party? Yes. 10 Α. 11 Q. And the fact that any settlement negotiations, to the extent they 12 13 are covered by 408, are confidential? MR. TOTO: I object to form. 14 15 You may answer. 16 Α. Yes 17 Well, why would it -- why was there an endorsement of subject to FRE 408

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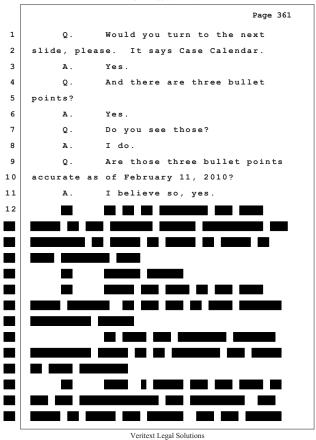
Page 359 1 8 Q. The next bullet point says 9 "Eight defendants have settled for a total 10 of 7.75 million for attorney fees, three 11 months early entry, and MFN." 12 Do you see that, sir? 13 Α. 14 ο. What is MFN? 15 Most favored nation. 16 20

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Page 360 1 The next bullet point says "Two 2 defendants settled for no early entry and 3 no attorney fees." 4 Is that a correct statement? 5 I believe so, yes. 6 The next bullet point, "Three defendants withdrew their ANDAs." 8 Is that a correct statement? 9 I believe so, yes. 10 And the last bullet point is 11 "One defendant entered into a consent 12 judgment." 13 Is that a correct statement as of February 11, 2010? 14 15 Yes. 16 

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1 Q. The information provided on this page refers to Forest's current settlement offer as of February 11, 2010?

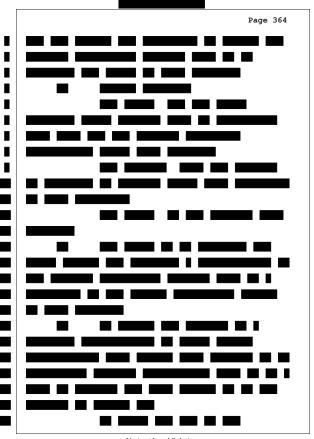
5 A. Yes.

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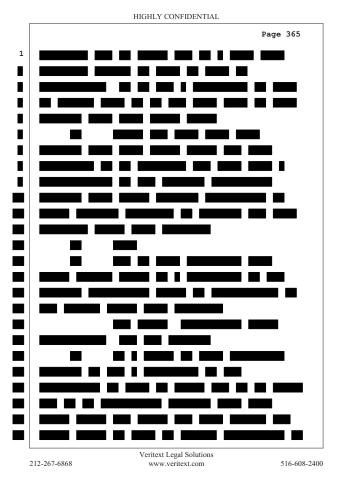
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Page 366 1 4 Who told you that, sir? Q. 5 MR. TOTO: Objection, 6 argumentative, lacks foundation. 7 it has always been the 8 philosophy of the senior management team at 9 10 transactions with people that we're in 11 12 

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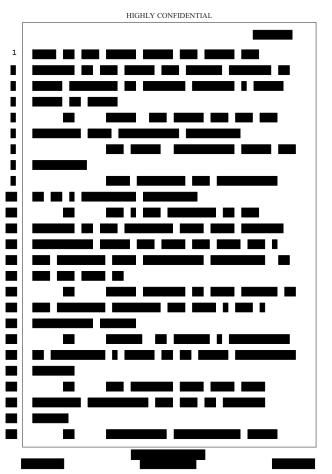
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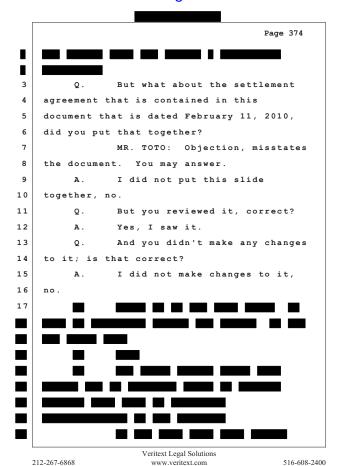
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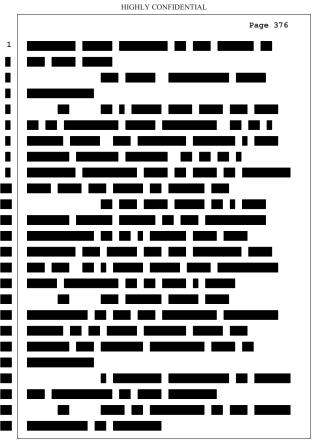
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Page 375 1 3 Q. Would you explain that to me, please? 4 5 So under the 6 Hatch-Waxman statute, first filers share 7 180 days of market exclusivity, and there are different events that will trigger 8 9 One would be that if the patent is 10 found invalid, for example, by the Federal 11 Circuit, then that would allow all of those 12 first filers to enter the market, meaning 13 sell their generic in the marketplace. 14 

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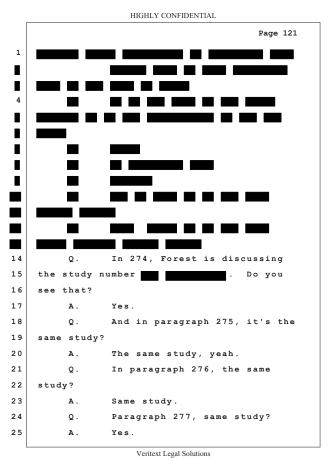
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# EXHIBIT 319

	Page 1
1	** HIGHLY CONFIDENTIAL **
2	UNITED STATES DISTRICT COURT
3	SOUTHERN DISTRICT OF NEW YORK
4	Civil Action No. 1:15-cv-07488-CM
5	x
6	
	IN RE NAMENDA DIRECT PURCHASER
7	ANTITRUST LITIGATION
8	
9	x
	September 7, 2017
10	8:15 a.m.
11	
12	
13	Videotaped Deposition of FOREST
14	LABORATORIES, LLC; ACTAVIS, PLC; FOREST
15	LABORATORIES, INC.; and FOREST LABORATORIES
16	HOLDINGS LTD., by CHARLES RYAN, Ph.D.,
17	taken by Plaintiffs, pursuant to Rule
18	30(b)(6) Notice, held at the offices of
19	Garwin Gerstein & Fisher LLP, 88 Pine
20	Street, New York, New York, before Todd
21	DeSimone, a Registered Professional
22	Reporter and Notary Public of the State of
23	New York.
24	
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Page 122 1 12 But in terms of studies that --13 these are the two that are identified, yes. 14 So in those paragraphs that 15 appear on the pages that you identified, there are no other studies referenced, 16 17 18 That's what I was looking for. 19 It doesn't appear that they reference other 20 studies in there, no. 21 24 MR. JOHNSON: Objection, lacks 25 foundation.

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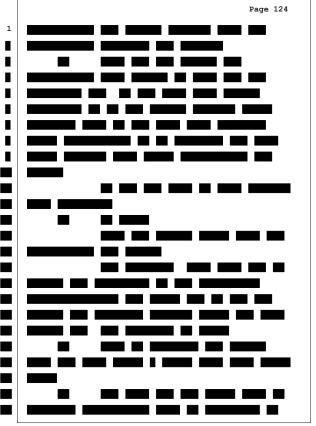
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Page 123 1 Are you asking what was 2 Forest's calculation that they submitted to 3 the FDA? 4 Q. Correct. 5 Let's see if -- I don't recall 6 it off the top of my head. I apologize. I 7 will see if I can find it in this document. 8 24 MR. JOHNSON: Objection.

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Page 125 1 23 MR. JOHNSON: Counsel, I don't know if it is a decent time for a break or It has been a little bit over an hour

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Page 126 1 we have been going. 2 MS. JONES: Sure, we can take a 3 break if you are ready to. THE VIDEOGRAPHER: We are going 5 off the record. The time is 10:50. This 6 ends disk two. (Recess taken.) 8 THE VIDEOGRAPHER: We are back 9 on the record. The time is 11:03. This is disk three. 10 11 BY MS. JONES: 12 I would like to go ahead and Ο. 13 mark as Ryan Exhibit 11 a document entitled Supplemental Scheduling Order. 14 15 (Ryan Exhibit 11 marked for identification.) 16 17 And just to provide a little 18 context, this is in connection with topic 10 on which you have been designated, which 19 is your estimate at or before the time of 20 21 settlement of the likely future timing of 22 the Namenda patent litigation absent 23 settlement. 24 And so Ryan Exhibit 11 is

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Document No. 117, filed July 17th, 2008.

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Page 127 Do you see that? 1 2 Α. 3 And in this Supplemental Scheduling Order, it says that "It is 4 ordered that this matter is scheduled for a 5 6 five-day bench trial beginning 9 a.m. on 7 April 5th, 2010 before Chief Judge Gregory M. Sleet." 8 9 Do you see that? 10 I do. 11 And then I would like to go 12 ahead and hand you what has previously been 13 marked Mears 10, Mears Exhibit 10. 14 And this document is a letter 15 that was sent to the Court dated March 16th, 2010. Do you see that? 16 17 Α. 18 Ο. And it is addressed to Chief 19 Judge Sleet? 20 Α. Yeah. 21 And in this letter, Mylan's counsel is requesting that the Court 22 preserve the April 5th trial date. Do you 23 24 see that? Α. Yes.

HIGHLY CONFIDENTIAL Page 128 1 And this letter states that it 2 was submitted with the consent of 3 plaintiffs, correct? 4 Α. 5 And plaintiffs would have 6 included Forest, correct? 7 Α 8 So this letter was sent with 9 the consent of Forest? 10 11 Veritext Legal Solutions

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term extension that was ultimately granted by the FDA was the maximum extension allowable; is that correct?

MR. JOHNSON: Objection to form, foundation.

So we were granted five years of patent term extension which statutorily is the longest period of time available,

Q. And do you have any reason to doubt that that extension -- that patent term extension extended the '703 patent to April 15th, 2015?

Α.

Does that sound right to you?

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Page 174 1 \_\_\_\_\_ If the pediatric exclusivity 10 11 has been granted prior to that four-year 12 date? 13 That's right. And is it correct that the 14

four-year date, in your understanding, the four-year date is for a generic who is filing a Paragraph IV certification ANDA?

Yes.

And if it were -- well, let's back up a little bit.

Could you explain your understanding of what a Paragraph IV certification is? I know I used the term, but I think we know what we are talking about, but I would like you to explain the

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meaning.

MR. JOHNSON: Objection, calls for expert testimony.

Sure. Under the Hatch-Waxman statute it is pretty comprehensive in terms of the roles and responsibilities of both parties, and one of them is that when a generic chooses to pursue an ANDA as part of that, if there is a patent listed in the Orange Book, they can file at, and if it is a five-year NCE, they can file at year four

If there is not a patent they have to wait until the fifth year. But in so doing one of the obligations is to send a fairly detailed letter to the patent holder and the NDA applicant, an explanation as to their view about the patents that have been listed in the Orange Book, the validity, infringement.

Why the generic believes the patent is either invalid or the generic product, proposed generic product, does not infringe the patent?

That's right.

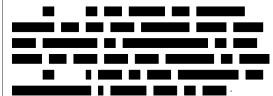
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ο. Or patents, if there are more than one, right?

> Α. Correct.

And so if a generic is filing an ANDA on the fourth day -- I'm sorry, on the four-year anniversary of NCE that would be a Paragraph IV certification ANDA; is that right?

That's right.



And do you have any understanding of what the incentives or benefits might be for a generic ANDA filer to file an ANDA with a Paragraph IV certification on the first day that they are eligible to file it?

Sure

MR. JOHNSON: Objection to form, also legal conclusion, expert testimony.

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I'm asking your understanding of the 180-day exclusivity period.

MR. JOHNSON: Same objections.

- Again, as I stated before, under the Hatch-Waxman statute, there's a number of quidance and standards about things and one of them, that if the first filer, so someone who files in this case on year four of a five-year, they get 180 days of market exclusivity before any other subsequent filers. So they get six months essentially to be, assuming their ANDA gets approved, to be on the market.
  - Exclusive of other generics?
- 15 Correct.

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also vaque.

generics.

- The brand would have the right to continue selling the brand?
- Α. Yeah, you can always sell your product.
- And in the context of Namenda, where there were a dozen or so generics who filed ANDAs with Paragraph IV certifications on that first day, do you have any understanding of how that works with the generic, with the 180-day

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exclusivity period?

MR. JOHNSON: Dr. Ryan, I think he is asking you a general question. It's not calling for privilege. But just let me caution you not to reveal any privileged communications or attorney work product in answering the question, which I will also object to as calling for expert testimony.

- So under the statute, all the first filers that would file on that four-year anniversary date, the first available date that you could file an ANDA. they would share that market exclusivity period of 180 days with the other filers, again, assuming their ANDA gets approved.
- And is it generally true to your knowledge, if you don't know I'm sure you'll tell me, that the more generic competitors there are on the market with an AB rated equivalent product, the lower the generic price would be in the market? MR. JOHNSON: Objection,

23 speculation, expert testimony.

24 So it's not an area that I work in, but it is my understanding that with

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greater competition on the market, it impacts price.

- And the more generic competitors in the market, the more the market is divided among those various competitors typically; is that correct? MR. JOHNSON: Same objections,
- Yes. So the more generics that are on the market, the more the market, you know, is fragmented between the various
- You would expect the market share of each generic to be less, correct?
- Not necessarily. I don't work in the generic industry, but it's not as if it's a piece -- a slice of pizza and everyone has the same size. So someone could capture much more market share than somebody else for any number of reasons.
- And those reasons would typically be related to competition in the market as far as you know?

MR. JOHNSON: Same objections.

MR. JOHNSON: Same objections.

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- It could be related to lots of things, quality, previous relationships, any number of reasons why someone would choose one generic over another.
- When the dozen or so generics filed their Paragraph IV certification ANDAs for Namenda did you have any expectations that the market would behave any differently than it typically did, the generic market I'm talking about?

MR. JOHNSON: Objection, vague, speculation, expert testimony.

- To be honest with you, it's not something I ever thought about.
- Do you recall which of -periodically for the rest of the afternoon I may refer to those dozen or so generics who filed on the first day they were eligible as first filers.
  - Α. Okav.
  - Is that okay?
- Sure
- So do you recall which of the first filers Forest sued for patent infringement?

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Page 181 I think we sued all of them. Do you remember which ones they ο. were? Again, it's not a quiz.

Α.

I will show you some documents later.

A

And you mentioned the Paragraph IV certification notice to Forest. Each one of those first filers provided a notice to Forest that they had filed an ANDA with a Paragraph IV certification?

Vac

And in each one of those notices to Forest explained that the generic either contended that the patent, the '703 patent, was invalid or that their proposed product wouldn't infringe the '703 patent; is that correct? MR. JOHNSON: Objection to

form.

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Or both. Q.

23 Typically it is almost always the same, which is that we don't infringe and if we do infringe the patent is

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invalid You don't recall any exceptions ο. for any of the first filer notices that you received for Namenda? I don't recall an exception ever.

Do you recall if there were any generic companies that filed Paragraph IV ANDAs after the first filers did?

Α. My recollection is that there 10 11 were maybe one or two, but there were a 12 couple of people that did file after.

> Do you recall who they were? No, I don't recall who they Α

15 were.

> Do you know if Forest filed patent infringement suits against them?

18 I think we did, but I -- I would imagine we did but I can't say for 19 20

Are you familiar with the term 30-month stay in the context of Hatch-Waxman litigation?

24 Yes.

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0 What's your understanding of

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what a 30-month stay is? MR. JOHNSON: Objection, expert testimony. Go ahead.

So a 30-month stay is a period of time in which the FDA is not going to approve, and while you are litigating it you have essentially like a year and a half without concern about the ANDA getting approved.

> Q. Two and a half years?

Two and a half years, sorry.

Do you know or recall when the 30-month stays that were triggered by Forest's patent infringement suits with respect to Namenda IR were set to expire? MR. JOHNSON: Objection,

17 foundation.

> A I'm trying to think of the year. So it was April -- it was almost a year after the last settlement, so whatever month we settled with Mylan, was July, I think it was April the following year. I think that's right.

Did, I probably should have Ο. asked this first, or before the last

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question, did Forest file its patent

infringement suits against all of the first 2 3 filers in time to trigger a 30-month stay for each as far as you recall?

MR. JOHNSON: Objection.

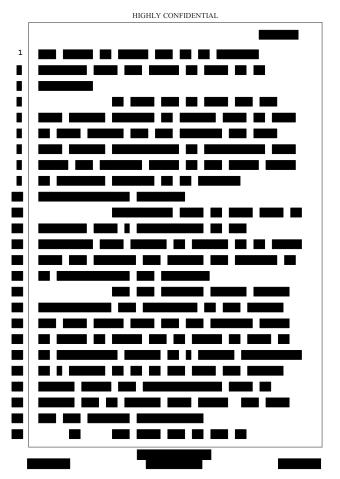
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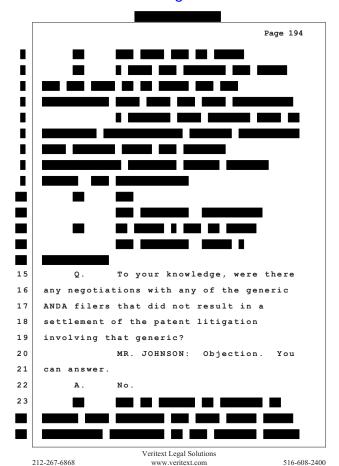
I don't actually recall.

Earlier this morning you identified two firms that represented Forest as outside counsel in the patent infringement litigations, Kirkland & Ellis and Jones Day, are those the two?



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HIGHLY CONFIDENTIAL Page 196 1 14 15 review that document. My first question is 16 if you recognize it. Answer when you're 17 ready. 18 I will represent, while you are 19 looking at that, that the document is a 20 printout from the Securities and Exchange 21 Commission website. 22 MR. JOHNSON: I will just 23 object to the extent this document hasn't 24 been produced in this case and we haven't had the opportunity to review it before

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HIGHLY CONFIDENTIAL Page 197 1 Dr. Ryan's being examined on it. So it appears to be a 10-Q for 2 the quarter ending September 30th, 2009 for 3 Forest Laboratories, Inc. Do you know what a 10-Q is, Dr. Rvan? A Did you have any role in 8 9 preparing this -- well, strike that. You were at Forest, correct, 10 11 during the quarterly period ended September 12 29th -- sorry, September 30th, 2009, 13 correct? Α. 14 Yes 15 Do you recall having any role in drafting any portion of this document? 16 17

communication by Forest, whether it is a 10-Q, 10-K, press release, any language with respect to intellectual property would either have been provided by me, or, at the very least, have been reviewed by me.

And which portions?

So with any public

MR. JOHNSON: Well, objection.

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So I see that there are things with respect to, for example, on page 14, legal proceedings, talking about the Lexapro patent infringement dispute, I would have either provided that language, or, at the very least, reviewed it before it was disclosed, but I don't recall anything in particular relative to this filing.

- Q. And you pointed out some language on page 14, it's the Legal Proceedings section, number 12, and it continues on to page 15 and there is some language there about the Namenda patent lawsuits. Do you see that?
- Do you recall having any role in preparing or reviewing this prior to the filing?
- I would have had a role. Sitting here today, I can't recall specifically this filing or this particular passage, but I would have -- I would have participated in this, or at least reviewed

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Do you have any reason to believe that any of the representations in this section are incorrect?

MR. JOHNSON: Objection.

- Or inaccurate?
- Α
- 0 Okay. You can set the document aside.

Dr. Ryan, during settlement negotiations with the various generics, do you recall discussions about when the generic companies would be permitted to launch their generic versions of Namenda

MR. JOHNSON: You mean discussions with the generics? MR. RAPHAEL: Yes.

- Can you tell me what you recall about those discussions?
- I recall that we had taken the position that they could come onto the market three months earlier than the expiry of the patent.
  - And at the time of the

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negotiations, Forest had not applied for or been granted pediatric exclusivity, is that correct, for the '703 patent?

I don't recall.

Do you recall any generics attempting to negotiate for an earlier launch date than three months prior to the expiration of the '703 patent?

So we certainly had in any settlement negotiation we talked about a variety of things including launch date. would be surprised if none of them -- none of them ever tried to advance for more. don't really recall. It was something that we were pretty firm on out of the gate.

Do you recall generics expressing concern to you about other generics getting better deals or earlier launch dates in negotiations with Forest?





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Page 202 1 Do you recall any discussions 2 with other individual generics about 3 concerns regarding other generics getting better deals or earlier launch dates? 4 5 6 MR. JOHNSON: Objection. 7 

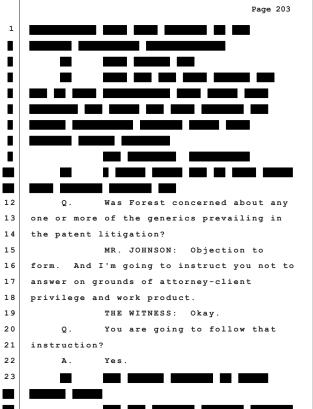
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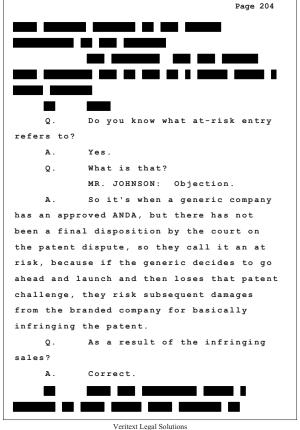
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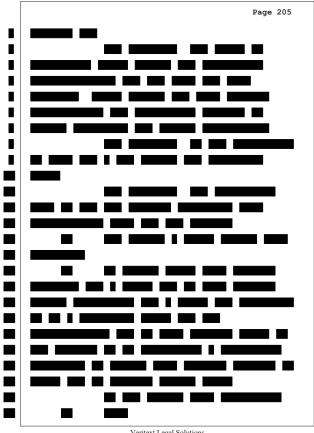
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HIGHLY CONFIDENTIAL Page 209 1 16 And I assume that would mean 17 18 discussions about that with generics? 19 That's right, I don't recall 20 that. 21

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In settlement negotiations with did Forest tell any of the generics that it wanted them to acknowledge

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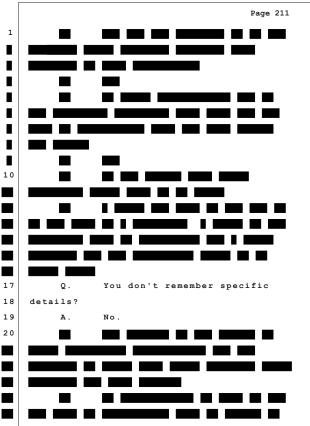
19 Do you recall specific

20 discussions about that?

I recall that we had discussions about that. I don't recall the specifics of it, but it is something that I remember did come up as part of the settlement discussion.

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Page 212 1 5 Do you recall if they did in 6 fact acknowledge that in the settlement 7 agreements? 8 I don't recall specifically. 9 They did. It's in there. 10 

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Page 213 1 2 THE VIDEOGRAPHER: We are going 3 off the record. The time is 1:40. This ends disk three. (Recess taken.) 6 (Ryan Exhibit 16 marked for 7 identification.) 8 THE VIDEOGRAPHER: We are back 9 on the record. The time is 1:55. This is disk four. 10 11 BY MR. RAPHAEL: 12 ο. Dr. Ryan, you have been handed 13 what the reporter has marked as Exhibit 16. My first question, again, is if 14 15 you recognize the document. I will give you a minute to review. 16 17 And while you do that, I will 18 note for the record that it has Bates numbers FRX-AT-04304905 through 914. 19 20 Do you recognize this document, 21 Dr. Ryan? 22 Α. 23 It appears to be -- it appears to be meetings of minutes -- strike that. It appears to be minutes of a

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Page 214 1 meeting of the Forest Laboratories Holding, Ltd. board of directors; is that correct? 2 3 And that meeting was held it 5 appears on March 12th, 2008; do you see that? 6 7 Α 8 In Bermuda; do vou see that? 9 10 Do you recall being present at 11 that meeting? 12 I recall that I was Α. 13 participating by phone. Oh, I see. Hopefully you were 14 15 in a nicer place than Bermuda. I don't think so. 16 Α. 17 MR. JOHNSON: I'm not sure 18 there are. 19 Q. Did you have any role or participate in the drafting of these 20 21 minutes, Dr. Ryan? 22 The preparation of the minutes, 23 24 And I will note that there are large portions of this exhibit that are

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redacted, so there are only -- I guess we're talking about the portions that aren't redacted.

Which portions did you have a role in preparing?

MR. JOHNSON: I just caution you, Dr. Ryan, not to reveal any privileged information in answering. But go ahead.

So I would have provided Α. just --

MR. JOHNSON: Again, a caution regarding privilege or work product, but if you can answer without that.

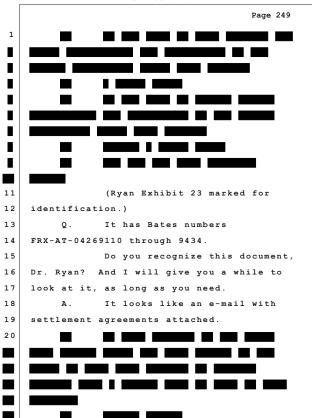
THE WITNESS: So can I answer in terms of what I would have done? MR. JOHNSON: I think you can answer generally as to what you would have done, but if you provided any legal advice to Forest or the board regarding these minutes or if you counseled anyone on what they should say, then please don't discuss the substance of any such attorney-client communications.

THE WITNESS: Okay.

I would have drafted the

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1 paragraph on page 7 and may have -- may 2 have participated in drafting what's on page 3. 3 Page 7 is the page with Bates ending 911, correct? 5 6 Right. 7 Veritext Legal Solutions



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Page 250 1 And the date is August 24th, 2 2009; do you see that? 3 Α. And any reason to believe that you didn't receive this e-mail from Eric Agovino on the date shown here? 6 Nο 8 With the exception of the 9 settlement chart, which I believe was withheld from production, it appears that 10 11 the attachments to this e-mail follow, and 12 specifically they are draft agreements. 13 settlement and license agreements for 14 Wockhardt, Apotex, Amneal, Cobalt, Lupin, 15 Mylan, Orchid, Sun, Teva and Upsher-Smith. Do you agree with that? 16 17 18 Q. Do you know why Mr. Agovino is 19 sending these draft agreements to 20 Mr. Jochum? 21 MR. JOHNSON: Dr. Ryan, you can 22 answer that yes, no, I don't know. 23 I don't know. 24 Are these, are the attachments

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to the e-mail, are they all draft

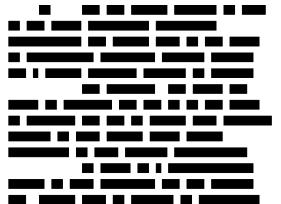
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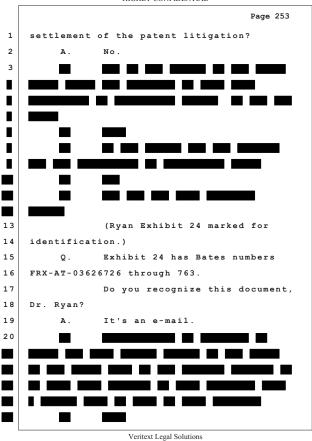
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agreements that Forest sent to the respective generics in August 2009?

- It appears so.
- Other than having not read each one, is there anything that stands out that would make you think that's not what the attachments are?
  - Α. No.
- And were each of these draft agreements prepared by Forest or someone acting on Forest's behalf?



HIGHLY CONFIDENTIAL Page 252 1 Do you know if each of the 3 Q. generics requested each of those 5 provisions? 6 And I say, by each of the 7 generics, I'm referring to the generics 8 whose agreements are attached to this 9 e-mail. 10 Α. 11 22 Do you have any reason to doubt that these were the amounts of attorneys' 24 fees that Forest offered to each respective generic as of the date of this e-mail in



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1 And the date is August 27th, 2 2009. Do you recall receiving this e-mail 3 in August 27th, 2009? 5 Any reason to believe that you 6 didn't? 7 Α. 8 Ο. Is this a document that Forest 9 maintains on its e-mail server in the 10 ordinary course? 11 MR. JOHNSON: Objection. 12 I assume so. 13 

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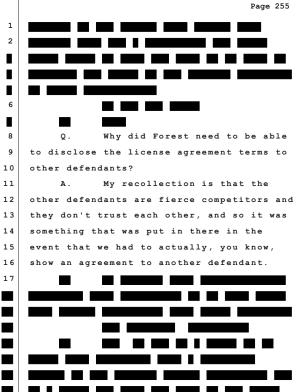
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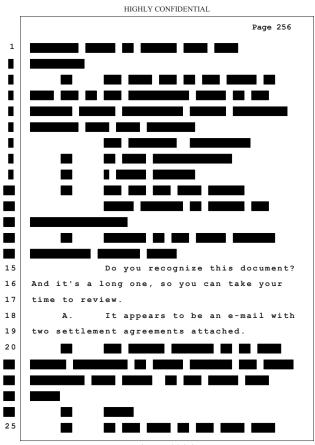
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### Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 104 of 171

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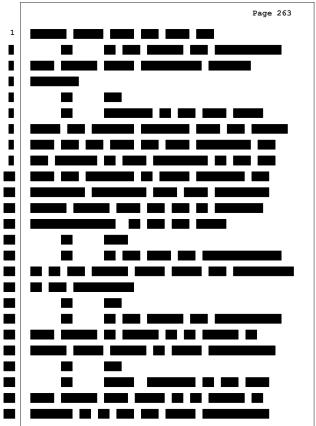
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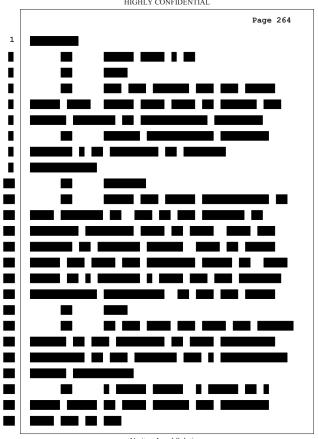
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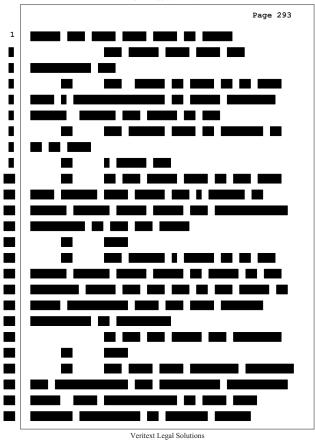


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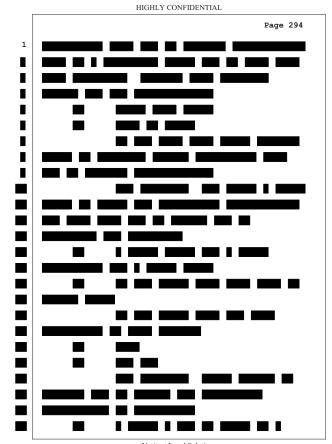
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This is document 36, which has Bates numbers FRX-AT-04320734 and it ends with 736.

Do you recognize this document? It appears to be an e-mail and

a single sheet that says Status of Memantine Patent Litigation

Do you have any reason to believe that you didn't receive this

> Α. No.

Q. Is this a document that Forest

	HIGHLY CONFIDENTIAL
	Page 296
1	would maintain in the ordinary course on
2	its e-mail server?
3	MR. JOHNSON: Objection.
4	A. I assume so.
5	Q. And the subject so the date
6	of this e-mail is January 21st, 2010. Do
7	you see that? The first page at the top.
8	A. Yeah.
9	
22	
	<b></b>
	<b></b>
_	

HIGHLY CONFIDENTIAL Page 317 1 Do you know what the Alphapharm 2 17 Q. Exhibit 44 has Bates numbers 18 FRX-AT-04247293 to 95. 19 Mr. Ryan, the exhibit appears to be three separate letters dated the same 20 21 22 Α. Yes. 23 Q. Do you recognize these letters? 24 Not really. That's what I find

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10 11

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funny.

Page 318 1 10 Q. Do you know, are these 11 documents that would be maintained by 12 Forest in the ordinary course of business? 13 MR. JOHNSON: Objection. 14 I believe so. 15 And were prepared by Forest employees in the ordinary course of 16 17 18 I believe so, ves. 19

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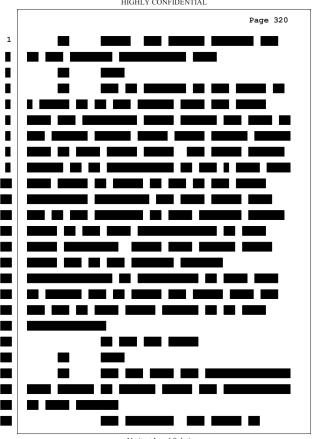
HIGHLY CONFIDENTIAL Page 319 1 2 3 8

Q. one exercised the most favored nation option? MR. JOHNSON: Objection.

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### EXHIBIT 320

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE: NAMENDA ANTITRUST

LITIGATION

1:15-ev-07488-CM-JCF

NOTICE OF RULE 30(b)(6) DEPOSITION OF DEFENDANTS FOREST LABORATORIES, LLC; ACTAVIS, PLC; FOREST LABORATORIES, INC.; AND FOREST LABORATORIES HOLDINGS LTD.

PLEASE TAKE NOTICE THAT, pursuant to Federal Rule of Civil Procedure 30(b)(6), Direct Purchaser Plaintiffs in the above-captioned litigation, by and through their counsel, will take the videotaped deposition upon oral examination of Defendants Forest Laboratories, LLC; Actavis, plc; Forest Laboratories, Inc.; and Forest Laboratories Holdings Ltd. (hereinafter and in Exhibit A referred to as "Forest"). The deposition, which will be stenographically recorded and videotaped before an officer duly authorized to administer oaths, will be held on July 19, 2017 at 9 am at the offices of Garwin Gerstein & Fisher LLP, 88 Pine Street, 10<sup>th</sup> Floor, New York, NY 10005. All counsel are invited to participate and cross examine.

NOTICE IS HEREBY GIVEN that, pursuant to Federal Rule of Civil Procedure 30(b)(6), Defendants are required to present one or more representatives to testify on their behalf and to give testimony on topics set forth in Exhibit A hereto. The person or persons so designated shall be required to testify concerning the matters known or reasonably available to Defendants with respect to each topic.

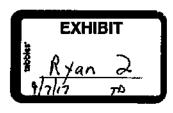
Dated: July 10, 2017

Respectfully submitted,

Rochester Drug Co-Operative, Inc. and the Proposed Class

JM Smith Corporation d/b/a Smith Drug Company and the Proposed Class

/s/ Dan Litvin



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### **CERTIFICATE OF SERVICE**

I hereby certify that on July 10, 2017, I served the foregoing Notice of Rule 30(b)(6) Deposition of Defendants Forest Laboratories, LLC; Actavis, plc; Forest Laboratories, Inc.; and Forest Laboratories Holdings Ltd. on counsel for Defendants via email.

/s/ Dan Litvin

### TOPICS FOR EXAMINATION

### EXHIBIT A

### DEFINITIONS

- 1. "'703 Patent' means U.S. Patent No. 5,061,703, and its corresponding ex parte reexamination certificate.
- 2. "ANDA" means Abbreviated New Drug Application as defined in 21 U.S.C. § 355(j).
- 3. "At-Risk Launch" means the launch of an FDA-approved drug (based on FDA review and approval) prior to a final judgment from which no appeal can be, or has been, taken in a patent litigation involving the FDA-approved drug.
- 4. "Authorized Generic" means a listed drug, as defined in 21 U.S.C. § 355(j), that has been approved under subsection 21 U.S.C. § 355(c); and is marketed, sold, or distributed directly or indirectly under different labeling, packaging, product code, labeler code, trade name or trade mark than the listed drug.
- 7. "Generic," "AB-rated generic," "generically equivalent product," or "generic drug equivalent" means a pharmaceutical or drug product that has been submitted to, or deemed by, the FDA as meeting the necessary requirements to be an AB-rated alternative to a Reference Listed Drug as such is defined by 21 CFR § 314.94(a)(3) and identified by the FDA.
- "Generic Namenda ANDA" means any of ANDA nos. 90-042 (Cobalt), 90-051 (Lupin),
   90-044 (Orchid), 90-052 (Teva), 90-043 (Upsher), 90-073 (Wockhardt), 90-045 (Barr), 90-048

(Dr. Reddy's), 90-050 (Genpharm), 90-041 (Interpharm), 79-225 (Mylan), 79-236 (Ranbaxy), 90-058 (Sun India and Kendle), 90-044 (Orgenus), 90-244 (Apotex), and any other ANDA that is, or at any time was, seeking FDA approval to market an AB-rated generic version of Namenda IR.

- 9. "Generic Namenda Competitor" means any entity seeking to produce, market, sell or promote a Generic Namenda Product, including but not limited to Barr Pharmaceuticals, Inc. ("Barr"); Teva Pharmaceuticals USA, Inc. ("Teva"); Cobalt Laboratories, Inc. ("Cobalt"); Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); Lupin Pharmaceuticals, Inc. ("Lupin"); Upsher-Smith Laboratories, Inc. ("Upsher-Smith"); Wockhardt Limited (Wockhardt"); Mylan Pharmaceuticals, Inc. ("Mylan"); Genpharm ULC and Genpharm, L.P. (jointly, "Genpharm"); Interpharm Holdings, Inc. and Interpharm Inc. (jointly, "Interpharm") (whose interests in the suit were soon to be acquired by a wholly owned subsidiary of Amneal Pharmaceuticals, LLC ("Amneal"); Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and Dr. Reddy's Laboratories Ltd. and/or Dr. Reddy's Laboratories, Inc. (jointly, "Dr. Reddy's").
- 10. "Generic Namenda Product" means a drug product that is or was the subject of a Generic Namenda ANDA.
- 11. "Lexapro" means any drug product that is or was described and the subject to NDA No. 21-323 (or any variant thereof), or any generic pharmaceutical product in which Lexapro is the Reference Listed Drug, regardless of, among other things, the dosage strength, dissolution rate, package size.

- 14. "Namenda IR" means the branded oral pharmaceutical containing the active ingredient memantine hydrochloride, marketed and sold under the trademark or name "Namenda," "Namenda®," "Namenda 5mg," or "Namenda 10mg," that is the subject of NDA No. 21-487. For avoidance of doubt, "Namenda IR" does not refer to "Namenda Oral Solution" "Namenda XR," or any generic equivalent to those drugs.
- 15. "Namenda Patents" means collectively, the '703 Patent and any other patent You contend would have affected any Generic Namenda Competitor's right, ability or willingness to market its Generic Namenda Product.
- 16. "Namenda Patent Litigation" means any patent infringement litigation involving a Generic Namenda Product or Generic Namenda ANDA including the following patent infringement lawsuits: (1) all lawsuits consolidated in *Forest Laboratories, Inc. v. Cobalt Laboratories Inc. et al.*, Civil Action No. 08-cv-0021-GMS-LPS (D. Del.) (consolidated); (2) *Forest Laboratories, Inc. et al. v. Orgenus Pharma, Inc. et al.* Civil Action No. 09-05105-MLC-DEA; *Forest Laboratories, Inc., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 1:14-cv-00833-LPS; and (3) any other patent infringement lawsuit against a Generic Namenda Competitor.
- 17. "Namenda XR" means the branded oral pharmaceutical containing the active ingredient memantine hydrochloride, marketed and sold under the trademark or name "Namenda XR" or Namenda XR®," that is the subject of NDA No. 22-525.
- 18. "Paragraph IV ANDA Certification" means a certification under section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. that a relevant patent is invalid, unenforceable, or will not be infringed.

- 20. "Pediatric Exclusivity" means the period of regulatory exclusivity as described in 21 U.S.C. § 355a, and analogous provisions.
- 21. "Reference Listed Drug" means the listed drug identified by the FDA as the drug product upon which the applicant relies in seeking approval of its Abbreviated New Drug Application as defined in 21 U.S.C. § 355(j).
- 22. "Teflaro" means any drug product that is or was described and the subject to NDA No. 20-327 (or any variant thereof), or any generic pharmaceutical product in which Teflaro is the Reference Listed Drug, regardless of, among other things, the dosage strength, dissolution rate, package size.
- 23. "You," "Your," and "Forest" mean Forest Laboratories, LLC; Actavis, plc; Forest Laboratories, Inc.; and Forest Laboratories Holdings Ltd. and any of their parents, subsidiaries, divisions, subdivisions, affiliates, predecessor and successor entities, partners, officers, directors, employees, agents, independent contractors, legal counsel, or any other person acting, or purporting to act, on its (or their) behalf.
- 24. The terms "and," "or," and "and/or" shall be construed in the conjunctive or the disjunctive, whichever makes the meaning more inclusive.

### **TOPICS FOR EXAMINATION**

### A. Patent Related Topics

1. The identity of the Namenda Patents.

- 2. Your subjective views and beliefs at the time of the Patent Litigation Settlements as to the strengths and weaknesses of the Namenda Patents in terms of (a) claim scope, (b) validity, (c) enforceability, (d) infringement by any Generic Namenda Product(s) and/or Generic Namenda ANDA(s), and (e) the validity and effect of any patent term extension.
- 3. Your subjective views and beliefs at the time of the Patent Litigation Settlements regarding the strength of Your position in the Namenda Patent Litigation regarding claim construction, infringement, validity, and patent term extension validity, including Your perceived likelihood of success with respect to each of those issues.
- 4. The positions You took, including the legal arguments You made and the factual evidence You relied upon, in the following document: Exhibit 11 to Document No. 474-1 in *Forest Laboratories, Inc. v. Cobalt Laboratories Inc. et al.*, Civil Action No. 08-cv-0021(D. Del.).
- 5. Your basis for refuting the legal arguments and factual evidence offered by Mylan Pharmaceuticals, Inc. in the following document: Exhibit 12 to Document No. 474-1 in *Forest Laboratories, Inc. v. Cobalt Laboratories Inc. et al.*, Civil Action No. 08-cv-0021(D. Del.).
- 6. The factual and legal basis for Your contention in the Namenda Patent Litigation that the asserted Generic Namenda Products were infringing or would directly or indirectly infringe the '703 Patent.
- 7. The factual and legal basis for Your contention in the Namenda Patent Litigation that the claims of the '703 Patent: (1) were patentable subject matter under 35 U.S.C. § 101; (2) were novel and non-obvious under 35 U.S.C. § 102-103; (3) satisfied the enablement, definiteness, and written description requirements of 35 U.S.C. § 112; and (4) were not illegally broadened under 35 U.S.C. § 305.

- 8. The factual and legal basis for Your contention in the Namenda Patent Litigation that the patent term extension for the '703 Patent was valid.
- 9. Your estimate, budget, or forecast, at or before the time of settlement, of the amount of litigation expenses that You saved by settling the Namenda Patent Litigation.
- 10. Your estimate, at or before the time of settlement, of the likely future timing of the Namenda Patent Litigation absent the settlement.

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## EXHIBIT 323

### In The Matter Of:

THE PEOPLE OF THE STATE OF NEW YORK, v. ACTAVIS, PLC, and FOREST LABORATORIES, LLC,

November 11, 2014

Southern District Court Reporters

Original File EBBDACTF.txt

Num-1-Scripts) with Word Index

### THE PEOPLE OF THE STATE OF NEW YORK, V.

ACTAVIS, PLC, and FOREST LABORATORIES, LLC,

November 11, 2014

Ebbdact1 Saunders - direct Page 217 Ebbdact1 Saunders - direct Page 219 Hearing Hearing 1 our business works. Namenda IR patients switching to XR prior to generic entry, 2 Q. You agree that it was a key priority of Forest in 2 right? A. It could. January 2014 to continue fueling the shift of Namenda to Namenda XR, right? Q. And doing the forced switch would help the Namenda sales 5 A. We were and remain focused on promoting our newer, more stream -- doing the forced switch would help preserve the innovative product, which is Namenda XR. Namenda sales stream after Namenda IR generic manufacturers Q. And Namenda XR, according to the models we saw, has only a 7 enter the market, right? 8 chance of losing sales to generics whereas Namenda 8 A. Not necessarily. It would make us more competitive to be IR has a chance, right? able to compete against generics, absolutely. 10 A. I don't know. My personal view is that it is not that 10 Q. And to help preserve the --11 easy, but there are probably models that show that, as we have 11 A. That would be the goal. We'll see how it plays out. 12 Q. And so by doing the hard switch, Forest hopes to hold on to 13 Q. Now, this gets a bit confusing because the numbers are the a large share of its bases instead of losing them to generic competition? same but I want t now talk about a different conversion number. The percentages are the same. But now instead of talking about 15 A. That would be the hope as well but up against lots of barriers and obstacles. the Namenda XR conversion to generic Namenda IR, right, the 17 Q. And Forest modeled the improvements to its bottom line that 17 kind of reverse conversion, I want to talk about your efforts to convert patients on Namenda IR to Namenda -- to branded would result from the hard switch, right? Namenda XR, OK? 19 A. It certainly did, yes. 19 20 A. OK. 20 Q. Let's look at one of those documents. 21 Q. And the reason I did that preamble is because the Before we do, what is Merz, M-e-r-z? 22 number comes up again. I don't want people to get 22 A. Merz is a German pharmaceutical company. confused that it is the same number but it is a different 23 23 Q. And Merz developed Namenda, right? 24 24 A. Well, Merz developed memantine, which is the chemical name 25 When you started as CEO, Forest was predicting that it for Namenda. Forest actually developed Namenda in the United Ebbdact1 Saunders - direct Page 218 Ebbdact1 Saunders - direct Hearing Hearing of the Namenda IR States, did the clinical studies, did the clinical development 1 could switch approximately 1 patients to Numidia XR before generic entry without a forced and regulatory work with the FDA and the like. Merz did not do switch, right? 4 A. Before I started as CEO, I believe that was their 4 Q. OK. And Merz licenses Forest the right to Namenda? projection. 5 A. No, to the chemical memantine, which we then turned into Namenda. 6 Q. And Forest expected that implementing a forced switch would 7 allow the company to achieve a higher level of switching to 7 Q. Thank you. Thank you. 8 Namenda XR than it would be able to achieve otherwise, correct? 8 And you pay Merz a royalty for Namenda sales, is that right? 9 A. I believe that we thought if we did that, we would put 9 10 A. We have, almost 10 ourselves in a more competitive situation to do that but no or thereabouts. 11 guarantee 11 Q. OK. Let me show you a presentation that was developed to 12 Q. If the hard switch were properly executed, Forest would send to Merz in January 2014. In your binder it is tab 6. We can turn to the PowerPoint that's on the third. 13 achieve significantly higher levels of conversion from Namenda 13 14 IR to Namenda XR than it would have achieved absent the forced 14 If you could go to page 6 of that PowerPoint. switch, right? 15 Now, on page 6, it says that Namenda XR from the hard switch, right? 16 A. That was the goal. 16 17 Q. And in order to take advantage of the lower generic erosion 17 A. Yes. 18 rate for Namenda XR, you had to accomplish that switching 18 Q. Does that sound about right to you? before generics enter the market, correct? 19 A. I think that was the forecast that was put into this model. 20 A. That is correct. We'll see if it happens. 21 Q. And it's more difficult and expensive for you to promote XR 21 Q. And it says sales from a soft switch would only be 22 once generic IR enters the market, right? but sales from the hard switch would be 22 right? 23 A. It would be very, very difficult. 23 24 Q. And you felt it was important that any -- strike that. 24 A. That's what it says.

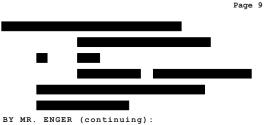
A forced switch could result in

25 Q. Does that seem right to you?

# EXHIBIT 328

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	NAMENDA DIRECT PURCHASER
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	October 11, 2017
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L 4	VIDEOTAPED 30(b)(6) DEPOSITION of
15	FOREST LABORATORIES (now ALLERGAN) and its
16	Representative JULIE A. SNYDER, taken by the
17	Plaintiffs, held at the aforementioned time and
18	place, before Sherri Flagg, a Registered
19	Professional Reporter, Certified LiveNote
20	Reporter, and Notary Public.
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- Ms. Snyder, you've just been handed Exhibit Number 1. Have you seen this July 10, 2017, deposition notice relating to patent topics before?
  - Α. No.
- ο. Are you aware that this notice requires Forest to produce a representative to testify on behalf of the company about the listed topics?
  - Α.
  - Will you turn to page 9, please. ο. MS. McDEVITT: Counsel, I'd just like to interject for the record that pursuant to the agreement to produce Ms. Snyder for this deposition on the three identified and in some instances narrow topics, I think those are the topics that we ought to be working off,

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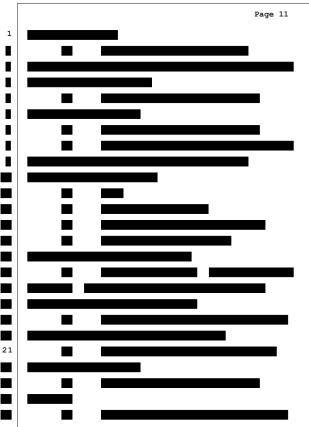
Page 10 1 not the notice which has been modified by 2 our subsequent agreement. 3 MR. ENGER: Understood. 4 BY MR. ENGER (continuing): 5 Are you Forest's designated 6 representative for topic number 9, which 7 relates to Forest's estimate, budget or forecast at or before the time of the 8 9 settlement of the amount of litigation expenses that Forest saved by settling the Namenda 10 11 patent litigation? 12 MS. McDEVITT: I'm just going to 13 interpose the same objection that I just 14 stated. 15 Can you repeat the question? 16 Are you Forest's designated 17 representative to testify on behalf of the 18 company about topic number 9, which is Forest's 19 estimate, budget or forecast at or before the time of settlement of the amount of litigation 20 21 expenses that Forest saved by settling the 22 Namenda patent litigation? 23 That is related to one of the 24 topics that I'm prepared to talk about.

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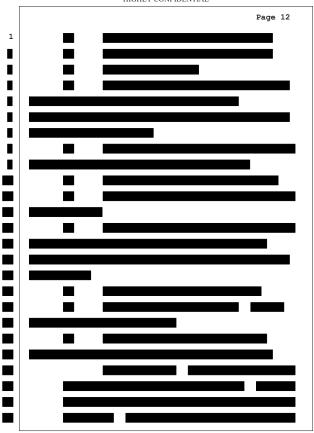
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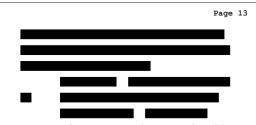
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Q. If you can. What are the things that Mr. Coletti told you about the things that go into litigation?

A. Sure. I mean, to -- litigation fees, attorney fees; there are, you know, a number of witnesses, fact witnesses, expert witnesses, that we would -- you know, that we'd incur costs related to those. I mean, there's everyday things like copying and graphic -- you know, graphics people to prepare things for court, there's hotel rooms, there's food; a number of different pieces of -- a number of different costs.

Q. Do you recall any other things that go into litigation besides attorneys' fees, fact witnesses, expert witnesses, copying, graphics personnel, hotel rooms and food?

A. That's what I recall off the top

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of my head.

Q. What did Mr. Coletti tell you
about things related to litigation costs?

MS. McDEVITT: Objection to form.

A. Litigation costs. I mean, we

talked about, you know, how they can vary. I mean, they can vary for a number of -- you know, a number of things, like all the things I provided there in the list. The costs vary, you know, depending on the case, depending on the time frame that they're -- the time frame for litigation. There's a lot of varying costs.

Q. Apart from certain costs can vary on a case-to-case basis and on a time-frame basis, did Mr. Coletti tell you anything else about things related to litigation costs?

A. I'm sure there were other things that we discussed in the conversation. But like I said, it's a very broad question.

Q. Nothing else comes to mind?

 ${\tt A.} \qquad {\tt Nothing \ else \ comes \ to \ mind, \ off}$  the top of my head.

24 Q. You also reviewed some documents in preparation for your deposition, correct?

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Page 16

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			Page 15
1	Α.	Yes, that's correct.	
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23	Q.	Could you briefly tell me	your
24	education hi	story since high school?	
25	Α.	Sure. I after high sc	hool I

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went to college, Drew University, with a degree in applied math; and then I got an MBA from Rutgers University with a concentration in marketing.

Q. What year did you receive your degree from Drew University?

A. Are you asking my age now? 1996.

Q. I apologize. What year did you receive your MBA from Rutgers University?

A. I believe it was 2001.

Q. Briefly, again, tell me your employment history since graduating from University.

A. Sure. I spent a few months as a math teacher and that was probably about three months; and then I went to Prudential, worked in their actuarial department for about three years.

Then I -- I don't remember what was next. I went to the National Exchange Carrier Association and worked in their -- doing statistics for statistical modeling; and after that I went to Health Products Research and I did pharmaceutical analytic consulting about two years.

### Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 124 of 171

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Page 17

Then I went to Schering-Plough and spent about three years there in their business analytics group as well as marketing. And then I've been at Forest/Actavis/Allergan since 2007, working in the marketing group for the entire time.

- ο. Have you ever had any responsibilities for overseeing litigation?

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- Q. What are your responsibilities since you've been at Forest, Actavis and Allergan since 2007, briefly?
- I worked on the Namenda marketing team for the first three to four years, then moved over to launch one of our other products for about three years; and then came back to head up the Namenda franchise marketing team starting in -- I believe that was 2014.
- Did you work closely with attorneys involved in litigation?
- Not really, no. I've had conversations with them when I have a question but I don't really work closely with them.
- Do you have any personal ο. experience with litigation costs?

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Personal experience, no. Α.

- ο. You understand that this lawsuit involves the drug Namenda, correct?
  - Α.
- Apart from your work on the marketing team for Namenda, have you ever had any other Namenda-related responsibilities?
- It's all been on the marketing Α. team, yeah.
- Q. At a high level, what were your marketing responsibilities for Namenda?
- You know, it varied over the years, but I worked with the sales force communications creating materials with our ad agency, forecasting, non-personal promotion. Pretty much, you know, everything related to the brand from a marketing capacity.
- Were you involved with the Namenda Ο. patent litigation?
- Α.
- Q. Apart from preparing for this deposition today, did you ever speak with anyone about the Namenda patent litigation?
  - Not that I can remember.
    - Are you aware that there was a

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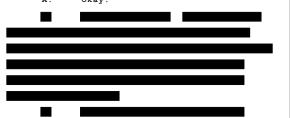
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settlement in principle of the Namenda patent litigation between Forest and Mylan in approximately March of 2010?

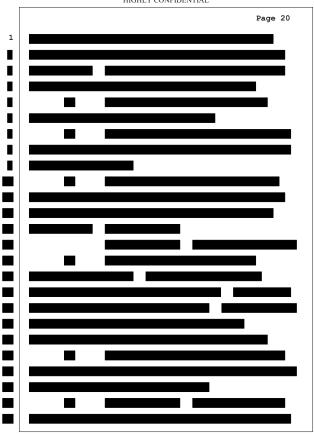
- I'm aware there was a settlement. I didn't know the date but that sounds right.
- At the time of the settlement in principle with Mylan and assuming that the Namenda patent litigation had not settled, how much did Forest expect to spend on attorneys' fees through trial and post-trial briefing?

MS. McDEVITT: Objection to form.

- Can you repeat that? That was long, that question.
- Yes, ma'am. Just to roadmap where we're going, we're going to talk about attorneys' fees and litigation savings associated with attorneys' fees.
  - Α. Okay.



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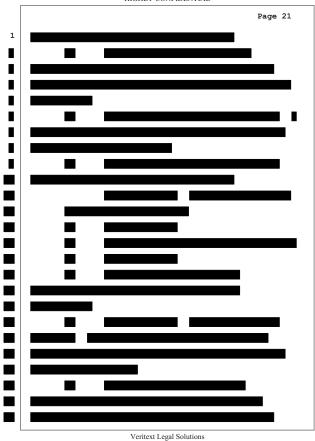
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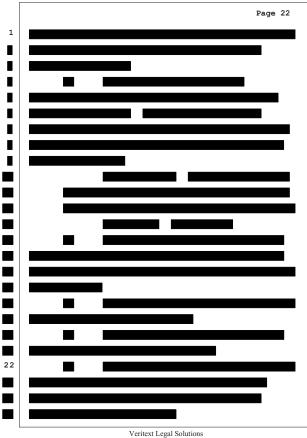
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At the beginning you told me a number of things that go into a litigation, things like fees, fact witnesses, expert witnesses, copying, graphics, hotel rooms and

Did the number that Mr. Coletti

provided you include each of those things? Include -- it would include estimates of those things, but there are things that could be, you know -- my understanding there are things that could happen during the trial that would require additional expert witnesses, additional fact witnesses. There could be other costs on top of what that was, an estimate, merely an estimate.

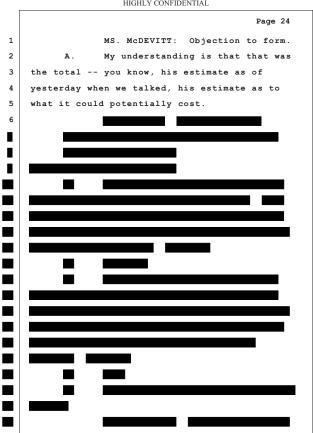
But the high single million dollar estimate that you were provided, it didn't carve out certain things like exclusive of hotel rooms, exclusive of food, to the best of your knowledge?

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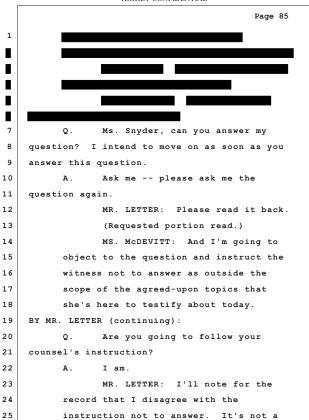
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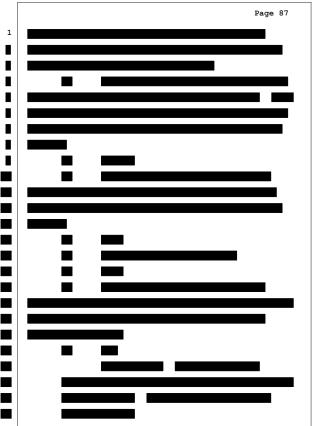
Page 86 1 privilege issue. 2 BY MR. LETTER (continuing): 3 So, Ms. Snyder, back to Solomon Exhibit 1, the list of previous 4 5 Forest-authorized generics in topic 3. Were you able to confirm that these were, in fact, 6 7 either launched by Forest or licensed to another company to launch authorized generic 8 9 versions of these particular drugs? 10 What are you looking at now? Α. 11 Yes, topic 3. It is on page 8, 12 which I believe is the last page. 13 So I mean, some of -- some of these products were Forest products, some of 14 15 them may not have been Forest products based on, you know, some of the acquisitions -- like 16 17 Carafate looks like something we acquired from another company so maybe -- so while it's 18 listed under Forest, I don't know if these were 19 20 Forest NDAs. 21

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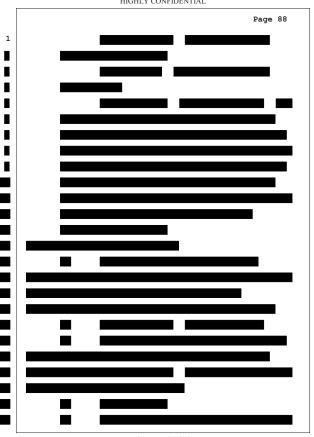
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Q. Since July 2015 -- and when I say "July 2015," that's when generic Namenda Immediate-Release products came on the market, so we're on the same page.

A. Um-hmm.

Q. Since July 2015, has Forest ever been unable to supply its customers' needs for Namenda Immediate-Release, either tablets, oral solution or authorized generic?

A. Not that I'm aware.

Q. In time periods that preceded July 2015, has Forest ever had a supply shortage for Namenda Immediate-Release tablets?

A. Not that I'm aware. I mean, I can't guarantee that there was never something on a backorder list or anything. You know, to the best of my knowledge, there was not a supply shortage.

 $\label{eq:Q.problem} \mbox{$\mathbb{Q}$.} \qquad \mbox{Are you familiar with the FDA's} \\ \mbox{list of drug shortages?}$ 

A. Yes.

 ${\tt Q.} \qquad {\tt I \ will \ represent \ to \ you \ that \ I}$  searched for drug shortages related to  ${\tt memantine \ hydrochloride \ and \ I \ never \ saw \ an}$ 

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appearance by Namenda Immediate-Release. Do you have any reason to doubt the results of that search?

A. No.

Q. Has Forest ever had -- has Forest ever encountered a supply shortage for memantine hydrochloride API?

A. Not that I'm aware.

Q. Does Forest always attempt to meet customer demand across all products?

MS. McDEVITT: Objection to form.

A. I can't speak to all products.

Obviously Forest would want to supply their customers with the products they need.

Q. Until the launch of generic

Immediate-Release Namenda in July 2015, was

Forest able to supply the entire memantine
hydrochloride market by itself?

MS. McDEVITT: Objection to form.

A. Can you say that again? I mean, I didn't -- can you read that back?

(Requested portion read.)

A. It's a broad question. I'm not sure what you're asking.

Q. Sure. So when I say "memantine

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hydrochloride market," I'm referring to that list that we went over earlier of Namenda Immediate-Release tablets, Namenda Immediate-Release oral solution, Namenda Extended-Release capsules, and Namzaric. Are we on the same page?

A. I'm just not sure what you're asking. Are you asking was there ever a shortage of any of those products? I'm not sure what you're asking.

Q. Sure, if you'd like to characterize it that way. Can you think of a shortage of any of those products ever?

A. Yes. There were times when there were products on backorder, absolutely.

 ${\tt Q.} \qquad {\tt Were \ any \ of \ those \ Namenda}$   ${\tt Immediate-Release \ products?}$ 

A. Like I said before, I mean, I don't recall a situation where there was an issue supplying Namenda Immediate-Release, but I -- you know, there could have been a

backorder at some time that I was not aware of.

Backorders are very common, you

24 know, so I don't know.

Q. Does Forest attempt --

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Forest/Actavis/Allergan, do they attempt to rectify backorders as soon as possible?

A. Of course.

 $\label{eq:Q.} \textbf{I} \ \mbox{am now going to switch gears}$  into the personal capacity declaration topic. Shall we take a break?

MS. McDEVITT: Do you want to take a break.

THE WITNESS: Sure.

MS. McDEVITT: Why don't we.

 $\label{eq:VIDEO TECHNICIAN:} \mbox{ The time on the } \\ \mbox{video monitor is 1:01 p.m.} \mbox{ We're off the } \\ \mbox{record.}$ 

(Lunch recess taken.)

### Case 1:15-cv-07488-CM-RWL Document 502-9 Filed 01/18/18 Page 128 of 171

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Ms. Snyder, please review that. While you're doing so, I will read for the record that this was a document produced by Forest to plaintiffs in this litigation bearing the Bates stamp FRX-AT-03794674. And let me know when you've had an opportunity to review.

(Perusing exhibit.)

Okav.

So, Ms. Snyder, very early on in this deposition when Mr. Enger was asking you questions, you said that, as part of the Namenda marketing team, one of the duties that you undertook was to write sales force communications. Do you recall that?

Yes.

Is this a communication to sales representatives that you wrote? And the reason I ask that is because it says "Thanks Julie" down at the bottom.

Right. I mean, it looks like something that, you know, I drafted based on this. But there's no information on whether I sent this or whether someone, you know, wrote it and I reviewed it. You know, people write -- on my team would write communications

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for me as well, so I'd have to see more detail to know for sure.

Is it fair to say that if someone on your team wrote this communication and it says "Thanks Julie," you would probably have reviewed it before it went out?

Α

Are you familiar with something called metadata?

> Α. Not much but yes.

Essentially it's data about the electronic file that the document comes from?

And the metadata for this ο. particular document indicates that it's from January of 2015. Do you have any reason to dispute that on the face of the document?

> Α. No.

So under the bold Important Message there, there's a paragraph that begins "As you know, the District Court." Do you see that?

Α.

24 And then it references the Court entering a preliminary injunction requiring

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Actavis to continue distribution of Namenda Immediate-Release tablets. Do you see that? And that's the same thing that is referenced in the Declaration of Julie Snyder that we talked about earlier, right, the injunction order?

Α.

Q. The second sentence in that paragraph that begins "As you know," says (as read):

> We are appealing this decision. Do you see that?

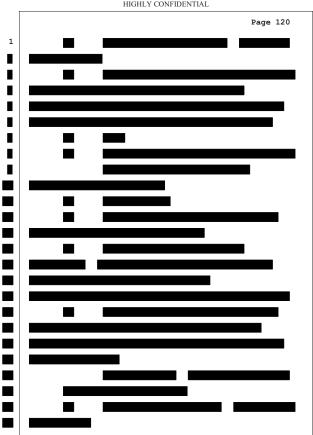
Α.

Why did Forest include information about appealing the injunction order?

I don't remember the details, but Α. it's factual.



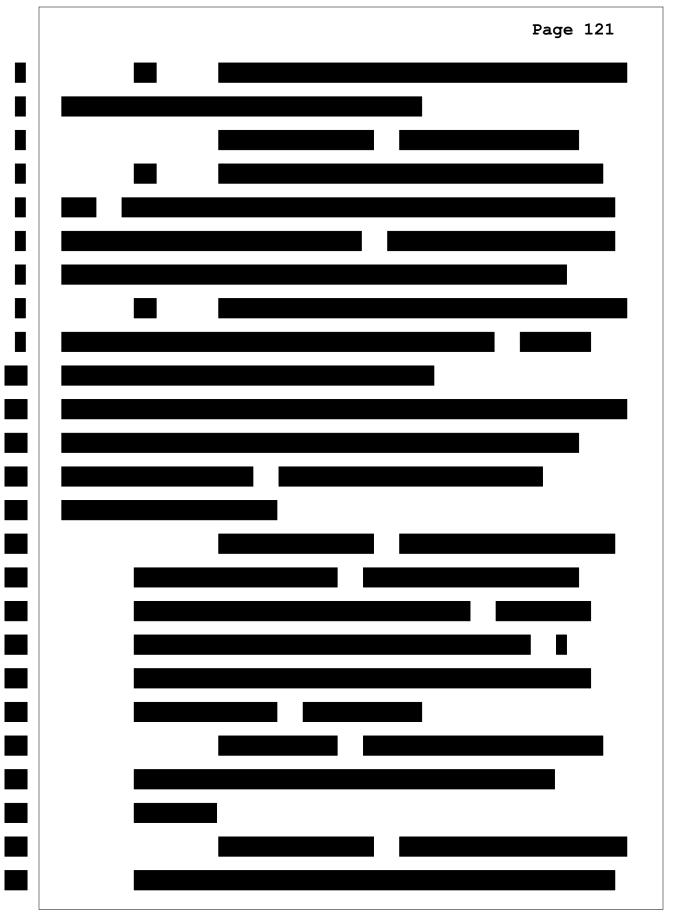
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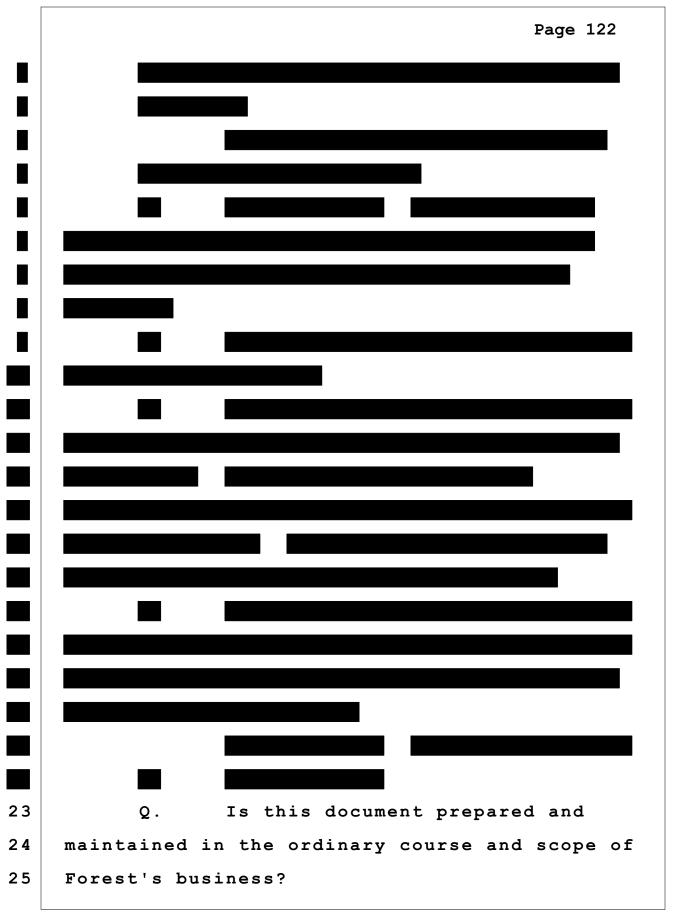


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	Page 123
1	A. Yes. We regularly communicate
2	with sales representatives.
3	
10	Q. And, Ms. Snyder, while you're
11	reviewing that, I will read for the record that
12	this was a document produced to us by Forest in
13	this case bearing the Bates stamp
14	FRX-AT-03983932 through 935. And let me know
15	when you've had an opportunity to review it.
16	A. (Perusing exhibit.)
17	Okay.
18	Q. Ms. Snyder, do you recognize this
19	document?
20	A. It looks familiar.
21	Q. Is this an e-mail from Amanda
22	Seeff? Is that how you say that, Seeff-Charny?
23	A. Yes, Amanda Seeff-Charny.
24	Q. To Lou-Ellen Barkan, Jed Levine
25	and Carol Berne dated January 14, 2015?

	Page 124
1	A. Yes.
2	Q. And it's got similar to what we
3	saw in Solomon Exhibit 3, I believe it was,
4	there is what appears to be an attachment that
5	says "Dear Customer1.13.15.pdf." Right?
6	A. Yes.
7	Q. Do you believe what is attached to
8	this e-mail to be that attachment, that is,
9	Dear Customer1.13.2015?
10	A. I would assume so, yes.
11	Q. You see that Ms. Charny is listed
12	as senior director healthcare alliance
13	development for Actavis. Do you see that?
<b>1 4</b>	A. Yes.
15	Q. Would that fall in the marketing
16	department?
17	A. No.
18	Q. So it's safe to assume that
19	Ms. Seeff-Charny does not report to you?
20	A. That's correct.
21	Q. So turning to the attachment that
22	begins on page Bates ending 934. Are you with
23	me?
2 4	A. Yes.
25	Q. It says from E-Pharm/Alert at the

	Page 125
1	top. Do you see that?
2	A. Yes.
3	Q. Is that a vehicle through which
4	Forest communicates to certain entities? Is
5	that a fair assessment?
6	A. Yes. That would be yes, that
7	would be a company that we would use to send
8	out communications to in this case it would be
9	pharmacies.
10	Q. So going back to Snyder Exhibit 6
11	for a moment, the entities that we discussed on
12	internal page 2, paragraph five, this would be
13	the template for communications about the
14	continued availability of Namenda
15	Immediate-Release to pharmacists, correct?
16	A. Yes, this would be to pharmacists.
17	Q. If you look in the body of that
18	e-mail after the salutation Dear Customer, it
19	starts "Forest Laboratories." Do you see that?
20	A. Yes.
21	Q. And the end of that first sentence
22	says Forest is appealing the court order to
23	continue the sales of Namenda Immediate-Release
24	tablets. Right?
25	A. Yes.

	Page 126
1	Q. If you now turn to the next page,
2	Bates ending 935, at the top it says from
3	E-LTC. Do you see that?
4	A. Yes.
5	Q. And, again, this is another entity
6	through which Forest disseminates
7	communications?
8	A. Yes.
9	Q. Is this related to any specific
10	entity as delineated in Snyder Exhibit 6?
11	A. Yes, long-term care facilities.
12	Q. And under the salutation Dear
13	Customer, the first sentence again says that
14	Forest is appealing the court order about
15	continued sales of Namenda Immediate-Release
16	tablets?
17	A. It says (as read):
18	Forest plans to continue the sale
19	of Namenda tablets in accordance with the
20	court order, which we are appealing.
21	Q. Is this e-mail and attachment
22	prepared and maintained in the ordinary course
23	and scope of Forest's business?
2 4	A. What do you mean by that?
25	Q. So it's a bit of like magic words

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- for lawyers. What I'm getting at is Amanda
  Seeff-Charny wasn't off doing her own thing
  that wasn't related to Actavis's business when
  she put together this e-mail and sent it to
  these various people, correct?
- A. Her job was working with the associations, this one in particular goes to the Alzheimer's Association, so that would have been in the normal course of business that she would communicate with them.
- Q. I see. So if you could turn to the first page again, Bates ending 932, you mentioned Alzheimer's. I think you said society?
  - A. Association.
- Q. Association, I'm sorry. So that would explain the alznyc.org e-mail addresses?
  - A. Yes.
- Q. I have a few more documents like this, but I'm going to try to short-circuit this by asking the question this way: All of the templates, as we talked about earlier, that discuss the continued availability of Namenda IR that went to the various entities, as delineated in paragraph five on internal page 2

Page 128 1 of Snyder Exhibit 6, did any of them not 2 mention the fact that Forest was appealing the 3 court order on the injunction? 4 MS. McDEVITT: Objection to form. 5 Α. I'd have to see all of them. can't quarantee that every one said it. 6 7 mean, there was a -- there was a template but there were a number of different communications 8 9 going out, so I don't know. 10 Let me try it this way: Do you, 11 as you sit here right now, recall any that did 12 not contain that language about appealing the 13 court order on the injunction? 14 We sent 900,000 communications. Α. 15 don't have every one memorized. I don't know. 16 I certainly appreciate that 17 answer. But you did say that you reviewed 18 templates related to them. 19 Α. Yes, yes. 20 I would imagine there probably 0. 21 weren't that many templates, right? 22 Α. Right, right. It was also several 23 years ago so I -- I mean, I can't guarantee 24 that every one had that language in it, but the 25 ones that we have here did.

# EXHIBT 330

		Page 1
1		
2	* HIGHLY CONFIDENTIAL *	
3	UNITED STATES DISTRICT COURT	
4	SOUTHERN DISTRICT OF NEW YORK	
5	Civil Action File No. 14-CV-7473	
6	x	
7	THE PEOPLE OF THE STATE OF NEW YORK, by	
8	and through ERIC T. SCHNEIDERMAN, Attorney	
9	General of the State of New York,	
10		
11	Plaintiff,	
12		
13	- against -	
14		
15	ACTAVIS, PLC and FOREST LABORATORIES, LLC,	
16		
17	Defendants.	
18	х	
19	October 22, 2014	
20	10:26 a.m.	
21		
	Videotaped Deposition of DAVID	
22	SOLOMON, pursuant to Notice, held at the	
	offices of White & Case LLP, 1155 Avenue	
23	of the Americas, New York, New York,	
	before Jineen Pavesi, a Registered	
24	Professional Reporter, Registered Merit	
	Reporter, Certified Realtime Reporter and	
25	Notary Public of the State of New York.	

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1	SOLOMON	. ШСШ У Сумалио	Page 54	1	Po SOLOMON - HIGHLY CONFIDENTIAL
1	SOLUMIUN -	HIGHLY CONFIDER	NIML	2	
				_	
					-
				6	Q. We're going to discuss Namenda 11:33:16A
				8	
				_	
					formulation of Namenda that was branded 11:33:28
					just as Namenda, unless you have a 11:33:31AM
					suggestion for a better way to refer to 11:33:35AM
				13	
				14	
				15	
				17	Q. Let's refer to the tablets as 11:33:50AM
					Namenda IR and if you want to talk about 11:33:52.
					•
					solution specifically. 11:33:56AM
				21	
					A. Okay, I can do that. (13.5.57A)
 		u explain what you me			
	y compliance.		2:18AM		
3	A. Sure.	11:32:2			
4	-	narmaceutical industry.			
	-	ocused on compliance v			
		tory standards around t			
7 1	•	de, distribution of our	11:32:35AM		
	•	ocused on issues relate			
8 p	o marketing pra	actices, also focused on			
8 p 9 to		Salara and	es 11:32:48AM		A Million Committee of the Advisory
8 p  9 to !0 th	he FCPA, the F	oreign Corrupt Practic		~ -	The transfer transfer representation of the commence of the transfer of the tr
8 p  9 to  0 th  21 A	he FCPA, the F Act, and making	g sure we were in comp	oliance 11:32:51AM		
8 p 19 to 20 th 21 A	he FCPA, the F Act, and making with that, focuse	g sure we were in comp ed on certain quality	bliance 11:32:51AM 11:32:54AM	21	
18 p 19 to 20 th 21 A 22 w 23 m	he FCPA, the FAct, and making with that, focused neasures, making	g sure we were in comp	oliance 11:32:51AM		

15 (Pages 54 - 57)

Page 70	Page 72
1 SOLOMON - HIGHLY CONFIDENTIAL	1 SOLOMON - HIGHLY CONFIDENTIAL
	2 molecule but from, how to put it, 11:54:03AM
	3 from as we think about the Alzheimer's 11:54:10AM
	4 market and the products that are being 11:54:17AM
	5 used for these patients, these are the H:54:18AM
	6 products that are being used and they are 11:54:21AM
	7 being used to treat the symptoms of 11:54:23ΔM
	8 Alzheimer's disease that's being exhibited 11:54:28AM
	9 by these patients. 11:54:31AM
	10 I think you know none of these 11:54:31AM
	11 cure it, right, tragically we don't have 11:54:33AM
	12 anything that cures Alzheimer's disease, 11:54:35AM
	13 but both of these drugs, Aricept and 11:54:37AM
	14 Namenda, are effective, you know, 11:54:42ΛΜ
15 Q. By activity, do you mean the 11:52:26AM	15 ameliorating some of the symptomology of 11:54:47AM
16 chemical activity or biological activity; 11:52:28AM	16 the disease. H:54:50AM
17 I'm sorry, can you explain that, please. 11:52:33AM	17 Q. You understand the term 11:54:53AM
18 A. Well, I am not a Ph.D. in this 11:52:35AM	18 AB-rated? H:54:55AM
19 area, so I have a fairly rudimentary 11:52:39AM	19 A. Yes. 11:54:56AM
20 understanding of it. 11:52:42AM	20 Q. Can you explain it to me. 11:54:57AM
21 Any two chemicals are going to 11:52:44AM	21 A. AB-rated is a term that's used 11:55:01AM
22 interact differently with your body, so 11:52:46AM	22 for generic products. 11:55:04AM
23 these are chemicals that are targeting the 11:52:50AM	So what a generic company is 11:55:08AM
24 brain and so, you know, any two chemicals 11:52:55AM	24 looking to do is seek approval of a drug 11:55:10AM
25 that, you know, that are used are going to 11:52:58AM	25 which they say is in fact chemically the 11:55:17AM
Page 71	Page 73
1 SOLOMON - HIGHLY CONFIDENTIAL	1 SOLOMON - HIGHLY CONFIDENTIAL
2 interact differently just because they are 11:53:01AM	2 same as a prior approved branded drug and 11:55:19AM
3 different, you know, they are different 11:53:03AM	3 an AB rating from the FDA is the FDA's way 11:55:23AM
4 structurally. 11:53:04AM	4 of saying, yes, that drug that the generic 11:55:26AM
5 So does Namenda act differently 11:53:06AM	5 is selling is in fact chemically identical 11:55:29AM
6 from Aricept in the brain, Aricept would 11:53:16AM	6 and therefore can be directly substituted 11:55:33AM
7 act differently from memantine, they are 11:53:19AM	7 without further intervention from a 11:55:38AM
8 different chemicals so each of them has 11:53:25AM	8 physician for the product. 11:55:41AM
9 their own that's why the FDA makes 11:53:27AM	9 Q. Is instant release memantine H:55:47AM
10 you can't just go to the FDA and say, hey, 11:53:30AM	10 AB-rated to extended release memantine? 11:56:08AM
11 this is kind of like this other drug you 11:53:32AM	11 A. No. 11:56:12AM
12 approved and so can I go sell it, the FDA 11:53:33AM	12 Q. Can it be? 11:56:I4AM
13 says no, the fact it is similar to 11:53:36AM	MR. TOTO: Object to form. 11:56:16AM
14 something else, you still have to go and 11:53:39AM	14 A. No, because in order to be AB 11:56:22AM
15 you still have to do that whole 11:53:40AM	15 rating you have to have the same dosing 11:56:24AM
16 development program I described to you 11:53:42AM	16 schedule as the drug AB rating isn't 11:56:26AM
17 before, you have to characterize it, you 11:53:43AM	17 ever used in this context. 11:56:32AM
18 have to do all of the pharmacokinetics, 11:53:45AM	18 It is used for a specific 11:56:35AM
19 you have to do all the toxicology, all the 11:53:47AM	19 generic equivalent, so, no, it would not 11:56:37AM
20 pharmacology work, you have to do all the 11:53:50AM	20 be AB-rated. 11:56:40AM
21 clinical studies, because little 11:53:51AM	
22 differences can, you know, be the 11:53:54AM	
23 difference between a done that you know 11.52.56 ANA	
23 difference between a drug that, you know, 11:53:56AM	
23 difference between a drug that, you know, 11:53:56AM 24 saves your life and one that kills you. 11:53:59AM 25 So any difference in a 11:54:01AM	

19 (Pages 70 - 73)

212-267-6868

## EXHIBIT 331

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE: NAMENDA ANTITRUST

LITIGATION

1:15-cv-07488-CM-JCF

NOTICE OF RULE 30(b)(6) DEPOSITION OF DEFENDANTS FOREST LABORATORIES, LLC; ACTAVIS, PLC; FOREST LABORATORIES, INC.; AND FOREST LABORATORIES HOLDINGS LTD.

PLEASE TAKE NOTICE THAT, pursuant to Federal Rule of Civil Procedure 30(b)(6), Direct Purchaser Plaintiffs in the above-captioned litigation, by and through their counsel, will take the videotaped deposition upon oral examination of Defendants Forest Laboratories, LLC; Actavis, plc; Forest Laboratorics, Inc.; and Forest Laboratories Holdings Ltd. (hereinafter and in Exhibit A referred to as "Forest"). The deposition, which will be stenographically recorded and videotaped before an officer duly authorized to administer oaths, will be held on July 18, 2017 at 9 am at the offices of Garwin Gerstein & Fisher LLP, 88 Pine Street, 10th Floor, New York, NY 10005. All counsel are invited to participate and cross examine.

**NOTICE IS HEREBY GIVEN** that, pursuant to Federal Rule of Civil Procedure 30(b)(6), Defendants are required to present one or more representatives to testify on their behalf and to give testimony on topics set forth in Exhibit A hereto. The person or persons so designated shall be required to testify concerning the matters known or reasonably available to Defendants with respect to each topic.

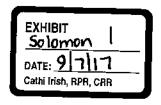
Dated: June 14, 2017

Respectfully submitted,

Rochester Drug Co-Operative, Inc. and the **Proposed Class** 

JM Smith Corporation d/b/a Smith Drug Company and the Proposed Class

/s/ Dan Litvin



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### **CERTIFICATE OF SERVICE**

I hereby certify that on June 14, 2017, I served the foregoing Notice of Rule 30(b)(6) Deposition of Defendants Forest Laboratories, LLC; Actavis, plc; Forest Laboratories, Inc.; and Forest Laboratories Holdings Ltd. on counsel for Defendants via email.

/s/ Dan Litvin

# **TOPICS FOR EXAMINATION**

# EXHIBIT A

## **DEFINITIONS**

- 1. "703 Patent" means U.S. Patent No. 5,061,703, and its corresponding *ex parte* reexamination certificate.
- 2. "ANDA" means Abbreviated New Drug Application as defined in 21 U.S.C. § 355(j).
- 3. "At-Risk Launch" means the faunch of an FDA-approved drug (based on FDA review and approval) prior to a final judgment from which no appeal can be, or has been, taken in a patent litigation involving the FDA-approved drug.
- 4. "Authorized Generic" means a listed drug, as defined in 21 U.S.C. § 355(j), that has been approved under subsection 21 U.S.C. § 355(c); and is marketed, sold, or distributed directly or indirectly under different labeling, packaging, product code, labeler code, trade name or trade mark than the listed drug.
- 5. "Authorized Generic Namenda IR" means an Authorized Generic version of Namenda IR.
- 7. "Generic," "AB-rated generic," "generically equivalent product," or "generic drug equivalent" means a pharmaceutical or drug product that has been submitted to, or deemed by, the FDA as meeting the necessary requirements to be an AB-rated alternative to a Reference Listed Drug as such is defined by 21 CFR § 314.94(a)(3) and identified by the FDA.
- 8. "Generic Namenda ANDA" means any of ANDA nos. 90-042 (Cobalt), 90-051 (Lupin), 90-044 (Orchid), 90-052 (Teva), 90-043 (Upsher), 90-073 (Wockhardt), 90-045 (Barr), 90-048

(Dr. Reddy's), 90-050 (Genpharm), 90-041 (Interpharm), 79-225 (Mylan), 79-236 (Ranbaxy), 90-058 (Sun India and Kendle), 90-044 (Orgenus), 90-244 (Apotex), and any other ANDA that is, or at any time was, seeking FDA approval to market an AB-rated generic version of Namenda IR.

- 9. "Generic Namenda Competitor" means any entity seeking to produce, market, sell or promote a Generic Namenda Product, including but not limited to Barr Pharmaceuticals, Inc. ("Barr"); Teva Pharmaceuticals USA, Inc. ("Teva"); Cobalt Laboratories, Inc. ("Cobalt"); Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); Lupin Pharmaceuticals, Inc. ("Lupin"); Upsher-Smith Laboratories, Inc. ("Upsher-Smith"); Wockhardt Limited (Wockhardt"); Mylan Pharmaceuticals, Inc. ("Mylan"); Genpharm ULC and Genpharm, L.P. (jointly, "Genpharm"); Interpharm Holdings, Inc. and Interpharm Inc. (jointly, "Interpharm") (whose interests in the suit were soon to be acquired by a wholly owned subsidiary of Amneal Pharmaceuticals, LJ.C ("Amneal"); Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and Dr. Reddy's Laboratories Ltd. and/or Dr. Reddy's Laboratories, Inc. (jointly, "Dr. Reddy's").
- 10. "Generic Namenda Product" means a drug product that is or was the subject of a Generic Namenda ANDA.
- 11. "Lexapro" means any drug product that is or was described and the subject to NDA No. 21-323 (or any variant thereof), or any generic pharmaceutical product in which Lexapro is the Reference Listed Drug, regardless of, among other things, the dosage strength, dissolution rate, package size.



- "Namenda IR" means the branded oral pharmaceutical containing the active ingredient memantine hydrochloride, marketed and sold under the trademark or name "Namenda," "Namenda®," "Namenda 5mg," or "Namenda 10mg," that is the subject of NDA No. 21-487. For avoidance of doubt, "Namenda IR" does not refer to "Namenda Oral Solution" "Namenda XR," or any generic equivalent to those drugs.
- 14. "Namenda Patents" means collectively, the '703 Patent and any other patent You contend would have affected any Generic Namenda Competitor's right, ability or willingness to market its Generic Namenda Product.
- 15. "Namenda Patent Litigation" means any patent infringement litigation involving a Generic Namenda Product or Generic Namenda ANDA including the following patent infringement lawsuits: (1) all lawsuits consolidated in *Forest Laboratories, Inc. v. Cobalt Laboratories Inc. et al.*, Civil Action No. 08-cv-0021-GMS-LPS (D. Del.) (consolidated); (2) *Forest Laboratories, Inc. et al. v. Orgenus Pharma, Inc. et al.* Civil Action No. 09-05105-MLC-DEA; *Forest Laboratories, Inc., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 1:14-cv-00833-LPS; and (3) any other patent infringement lawsuit against a Generic Namenda Competitor.
- 16. "Namenda XR" means the branded oral pharmaceutical containing the active ingredient memantine hydrochloride, marketed and sold under the trademark or name "Namenda XR" or Namenda XR®," that is the subject of NDA No. 22-525.
- 17. "Paragraph IV ANDA Certification" means a certification under section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. that a relevant patent is invalid, unenforceable, or will not be infringed.
- 18. "Patent Litigation Scttlement" means any agreement(s) to settle any or all claims in the Namenda Patent Litigation(s) including any agreement that Forest disclosed to the Federal Trade

Commission under MMA § 1112 pertaining to Namenda Patent Litigation(s), the Lexapro Amendment, and the Ceftaroline Agreement.

- 19. "Pediatric Exclusivity" means the period of regulatory exclusivity as described in 21 U.S.C. § 355a, and analogous provisions.
- 20. "Reference Listed Drug" means the listed drug identified by the FDΛ as the drug product upon which the applicant relies in seeking approval of its Λbbreviated New Drug Application as defined in 21 U.S.C. § 355(j).
- 21. "Teflaro" means any drug product that is or was described and the subject to NDA No. 20-327 (or any variant thereof), or any generic pharmaceutical product in which Teflaro is the Reference Listed Drug, regardless of, among other things, the dosage strength, dissolution rate, package size.
- 22. "You," "Your," and "Forest" mean Forest Laboratories, LLC; Actavis, plc; Forest Laboratories, Inc.; and Forest Laboratories Holdings Ltd. and any of their parents, subsidiaries, divisions, subdivisions, affiliates, predecessor and successor entities, partners, officers, directors, employees, agents, independent contractors, legal counsel, or any other person acting, or purporting to act, on its (or their) behalf.
- 23. The terms "and," "or," and "and/or" shall be construed in the conjunctive or the disjunctive, whichever makes the meaning more inclusive.

#### **TOPICS FOR EXAMINATION**

## A. Causation and Regulatory Related Topics

1. Your efforts to develop, manufacture, prepare for commercial marketing, and ultimately launch Authorized Generic Namenda including, but not limited to, Your efforts to obtain regulatory approval from the FDA, Your efforts to obtain raw materials and manufacture launch

7

quantities of Authorized Generic Namenda, and the impact of any Patent Litigation Settlement(s) on Your efforts and decision to develop, manufacture, prepare for commercial marketing, and ultimately launch Authorized Generic Namenda.

- 2. Your forecasts relating to Authorized Generic Namenda's unit and/or dollar sales, costs, and profits, as well as any planned, expected, or forecasted impact on Your sales, price(s), crosion rate(s), and/or profits from launching or abstaining from launching an Authorized Generic Namenda.
- 3. Your contemplated and/or actual launch dates and/or conditions of launch for Authorized Generic Namenda. Your historical policies and practices with respect to launching an Authorized Generic, including the reasons You decide, or You in the past have decided, whether to launch, or not launch, an Authorized Generic with respect to each of Your brand-name products, including, without limitation, Carafate Tablets, Flumadine Tablets, Lexapro Oral Solution, Lexapro Tablets, Namenda Tablets, Tessalon Capsules, and Urso Tablets.
- 4. Your efforts to obtain Pediatric Exclusivity for Namenda IR.
- 5. Communications with FDA concerning Pediatric Exclusivity for Namenda IR, including Communications interpreting and/or explaining Pediatric Exclusivity's effect on FDA approval of any Generic Namenda Competitor's Generic Namenda Product.
- 6. Your internal Communications concerning Pediatric Exclusivity for Namenda IR, including Communications concerning Pediatric Exclusivity's effect on FDA approval of any Generic Namenda Competitor's Generic Namenda ANDA(s).
- 7. Your beliefs concerning the effects of the any Patent Litigation Settlement(s) on any Generic Namenda Competitor's regulatory approval, manufacturing, launch preparations, launch, marketing, and/or sales of any Generic Namenda Product.

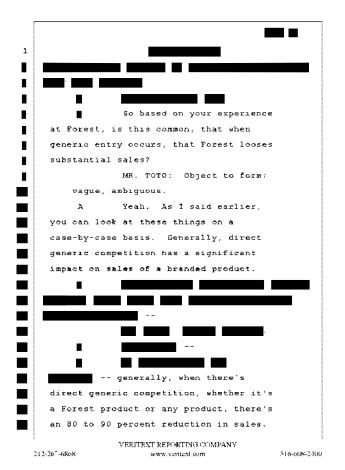
# EXHIBIT 347

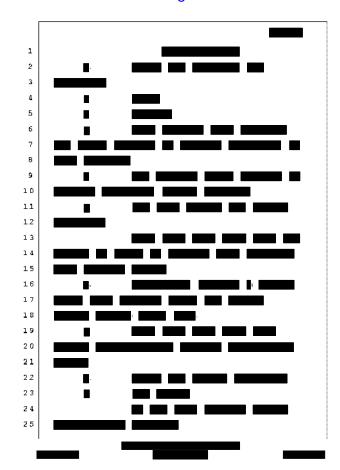
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4	In Re: Namenda 343 Statement
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7	State of New York
8	Office of the Attorney General
9	120 Broadway, 26th Floor, Antitrust Bureau
10	New York, New York 10271
11	
12	July 10, 2014
13	9:10 a.m.
14	
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16	Witness: William Meury
17	Reported By: Anthony Giarro
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21	* TRANSCRIPT OF PROCEEDINGS *
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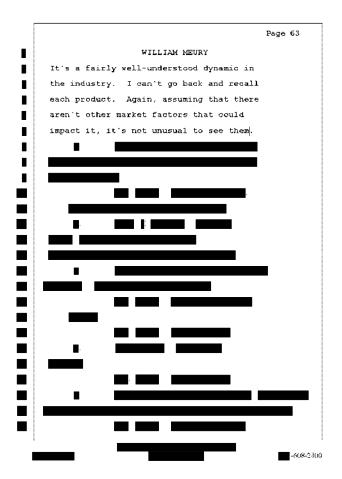
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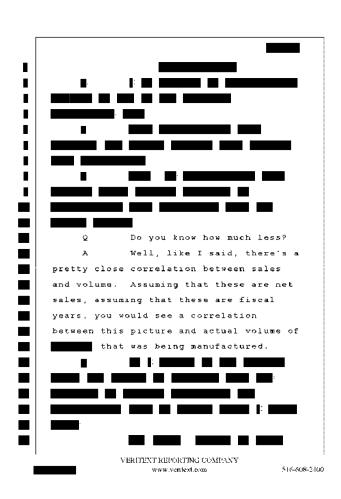
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# EXHIBIT 355

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	x	USDC SDNY DOCUMENT ELECTRONICALLY FILED DOC#:
IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION		DATE FILED: 5/93/2017  No. 15 Civ. 7488 (CM)

MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR COLLATERAL ESTOPPEL AND PARTIAL SUMMARY JUDGMENT ON COUNT ONE; DENYING PLAINTIFFS' AND DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT ON COUNT FIVE

McMahon, C.J.:

This action is a sequel to a 2014 antitrust lawsuit brought by the State of New York against Defendants Actavis PLC (now known as Allergan PLC) and Forest Laboratories, LLC (collectively, "Forest"), a pharmaceutical manufacturer. In the earlier case, New York asserted that Forest was attempting to effectuate an illegal "hard switch" product hop by removing its twice-daily Alzheimer's medication, Namenda IR, from the market prior to the entry of generic competition in order to force patients and their physicians to switch to its once-daily version of the same drug, Namenda XR. New York alleged that this hard switch would permit Forest to extend its monopoly over a leading treatment for moderate-to-severe Alzheimer's disease through the end of Namenda XR's patent exclusivity period in 2029.

On December 11, 2014, my colleague the Hon. Robert Sweet issued a preliminary injunction in that prior action, blocking Forest from restricting access to Namenda IR for the remainder of Namenda IR's patent exclusivity period and requiring Forest to affirmatively undo the effects of its announcement of the withdrawal. That ruling was upheld on appeal by the Second Circuit.

Plaintiffs J M Smith Corporation d/b/a Smith Drug Company ("Smith") and Rochester Drug Co-Operative, Inc. ("RDC," collectively with Smith, "Plaintiffs") are direct purchasers of Namenda, and allege that they (along with their proposed classes) were forced to pay supracompetitive prices due to Forest's anticompetitive conduct.

Before the Court are three motions: (1) Plaintiffs' motion for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134); (2) Plaintiffs' motion for partial summary judgment on Count Five (Dkt. No. 138); and (3) Defendants' cross-motion for partial summary judgment on Count Five (Dkt. No. 161).

According to Plaintiffs, the anticompetitive nature of Forest's hard switch was thoroughly litigated in the prior action brought by New York, and the Court should apply the principles of offensive non-mutual collateral estoppel to avoid relitigating those issues again. If Forest is estopped from relitigating the issues decided in Judge Sweet's opinion, they argue, Plaintiffs are entitled to summary judgment on the question of Forest's liability (but not causation or damages) with respect to Count One, which alleges a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. This motion is granted in part and denied in part.

In Plaintiffs' second motion, they assert that Forest, along with Defendants Forest
Laboratories, Inc., and Forest Laboratories Holdings Ltd. (collectively with Forest,
"Defendants"), entered into settlement agreements with various generic drug manufacturers to, in
effect, delay market entry of generic versions of Namenda IR until three months after Namenda
IR's patent exclusivity period expired. These agreements, they argue, illegally extended Forest's

<sup>&</sup>lt;sup>1</sup> Plaintiffs' motion at Dkt. No. 138 and Forest's cross-motion at Dkt. No. 161 were initially styled as motions addressing Count Three. After an inquiry from the Court (Dkt. No. 187), the parties clarified that both motions were intended to address Count Five (Dkt. Nos. 188, 194), a representation that the Court accepted. (See Dkt. No. 195.) All references to "Count Five" in this opinion correspond to references to "Count Three" in the motion papers.

patent license beyond the term of the patent and constituted a "naked restraint of trade" in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiffs seek partial summary judgment on Count Five solely on the issue of whether the settlement agreements constitute a *per se* restraint of trade (and again, not on issues of causation or damages). Defendants cross-move on the same issue, arguing that the settlement agreements were not *per se* anticompetitive, and seek summary judgment dismissing Count Five in its entirety. Both of these motions are denied.

# Background

The basic facts of this case were thoroughly reviewed in Judge Sweet's opinion granting a preliminary injunction to New York, New York v. Actavis, PLC (Namenda I), No. 14 Civ. 7473, 2014 WL 7015198, at \*1 (S.D.N.Y. Dec. 11, 2014),<sup>2</sup> the Second Circuit's decision affirming Judge Sweet's opinion, New York ex rel. Schneiderman v. Actavis PLC (Namenda II), 787 F.3d 638 (2d Cir.), cert. dismissed, 136 S. Ct. 581, 193 (2015), as well as in a prior decision of this Court denying Forest's motion to dismiss, Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC (Namenda III), Nos. 15 Civ. 6549, 15 Civ. 7488, 2016 WL 4992690, at \*1-\*8 (S.D.N.Y. Sept. 13, 2016). The summary of facts in the following pages is drawn from Namenda I, Namenda II, and Namenda III, as well as from Plaintiffs' Rule 56.1 Statement of Material Facts on Count One ("Pls.' Count One 56.1"), Dkt. No. 137, and Defendants' Response ("Defs.' Count One 56.1"), Dkt. No. 158, and Plaintiffs' Rule 56.1 Statement of Material Facts on Count Five ("Pls.' Count Five 56.1"), Dkt. No. 141, and Defendants' Response and Counter-Statement ("Defs.' Count Five 56.1"), Dkt. No. 164. Unless otherwise noted, these facts are

<sup>&</sup>lt;sup>2</sup> Unless otherwise noted, all references to the *Namenda I* opinion are to the public, redacted version.

undisputed, and I summarize the factual and procedural history of this litigation only to the extent necessary to decide the instant motions.

# I. The Parties

Forest manufactures and sells brand-name pharmaceutical products, including the prescription pharmaceutical memantine hydrochloride ("memantine"), which is sold in the United States under the trade names "Namenda" (referred to here as "Namenda IR" to distinguish from Namenda XR) and "Namenda XR." (Defs.' Count Five 56.1 ¶ 1). Memantine is a treatment for moderate-to-severe forms of Alzheimer's disease. Forest developed Namenda IR pursuant to a license and cooperation agreement with Merz GmbH & Co. KGaA, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Merz Entities"), which owned the relevant patent for a memantine-based drug.<sup>3</sup>

Plaintiff Smith is a South Carolina corporation that purchased Namenda IR directly from Forest and alleges that, during the class period, it paid prices higher than it would have absent Defendants' anticompetitive conduct. Plaintiff RDC is a New York corporation that also asserts that it purchased Namenda IR directly from Forest at supracompetitive prices.

# II. The Regulatory Scheme

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., governs the manufacture, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a pharmaceutical company must submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") before it may bring a new drug to market. See generally 21 U.S.C.

<sup>&</sup>lt;sup>3</sup> The Merz Entities were originally named defendants to some of the counts in the amended complaint, but per a stipulation of the parties, the Merz Entities were terminated as defendants and replaced by Defendants Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd., which are named as defendants to Counts Three, Four, and Five of the amended complaint. (See Dkt. No. 207.)

§ 355. Because the NDA must provide the FDA with sufficient scientific data to demonstrate that the new drug is safe and effective, the testing and approval process is generally "long, comprehensive, and costly." FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013).

Once approved, though, a patented drug enjoys a period of market exclusivity. That period ends when the drug's patent expires and one or more low-cost generic versions of the drug enter the market and compete with the brand-name drug — what is referred to as going off the "patent cliff." *Namenda II*, 787 F.3d at 643. Generic versions of a drug, or "generics," are "copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." FDA, *Understanding Generic Drugs*, http://l.usa.gov/1SjEIso (last visited May 22, 2017).

# A. The Hatch-Waxman Act

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98–417, 98 Stat. 1585, to serve the dual purposes of incentivizing pharmaceutical innovation (by granting patent extensions to brand-name drug manufacturers) and lowering drug prices for consumers (by encouraging competition from generic drugs). *Namenda II*, 787 F.3d at 643-44. To encourage innovation, the Hatch-Waxman Act provides brand-name drug manufacturers the opportunity to extend their exclusivity period beyond the standard 20-year patent term. To encourage competition from generics, the Hatch-Waxman Act makes it easier for generic manufacturers to get their drugs approved by the FDA.

As relevant here, the Hatch-Waxman Act provides two methods by which a brand-name drug manufacturer can extend its period of market exclusivity.

First, a manufacturer can seek an extension of its patent from the U.S. Patent and Trademark Office ("PTO") to account for the time the manufacturer spent obtaining approval

from the FDA for its brand-name drug. 35 U.S.C. § 156. That extension can last no more than five years. *Id.* § 156(g)(6).

Second, a brand-name drug manufacturer can obtain a six-month period of "pediatric exclusivity" if it conducts certain pediatric studies and the FDA determines that use of the drug in children may produce health benefits. 21 U.S.C. § 355a. A grant of pediatric exclusivity does not extend the length of the underlying patent, but can operate to exclude generic competition by delaying the date by which the FDA may approve generics for sale.

Under the Hatch-Waxman Act, the manufacturer of a generic version of an FDA-approved drug may file an Abbreviated New Drug Application ("ANDA"), which allows the generic manufacturer to rely upon the studies submitted by the brand-name drug manufacturer in connection with the original NDA to prove that the generic version of the drug is safe and effective. The ANDA filer must certify that its generic drug, among other things, has the same active ingredient as, and is "bioequivalent" to, the previously-approved drug. 21 U.S.C. § 355(j)(2)(A)(ii), (iv); Namenda II, 787 F.3d at 644. A generic drug is bioequivalent to the brand-name drug if it has the same "rate and extent of absorption" of the active ingredient as that of the brand-name drug. 21 U.S.C. § 355(j)(8)(B)(i). "In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time." Namenda II, 787 F.3d at 644.

When a generic drug manufacturer files an ANDA, it must certify one of four things:

(1) that the brand-name drug is not patented; (2) that the brand-name drug's patent has expired;

(3) that the brand-name drug's patent will expire prior to manufacture of the generic drug; or

(4) that the brand-name drug's patent is invalid or will not be infringed by manufacture of the

generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). This final route is called "Paragraph IV Certification." Namenda III, 2016 WL 4992690, at \*4.

The first manufacturer to file an ANDA with a Paragraph IV Certification may be granted a 180-day exclusive marketing period for its generic drug by the FDA. 21 U.S.C. § 355(j)(5)(B)(iv). This means that no other generic manufacturer's ANDA may become effective until "180 days after the date of the first commercial marketing of the drug" by the first ANDA filer. *Id.* § 355(j)(5)(B)(iv)(I).

Because the 180-day exclusivity period can be quite lucrative, generic manufacturers are incentivized to file an ANDA with a Paragraph IV Certification quickly, even if the brand-name drug's patent is ultimately found to be valid. However, the Hatch-Waxman Act provides that a Paragraph IV Certification is treated as an act of patent infringement and gives the holder of the brand-name drug patent the right to sue the prospective generic manufacturer within forty-five days of being notified of the filing of a Paragraph IV Certification. *Id.* § 355(j)(5)(B)(iii). If the brand-name manufacturer fails to bring suit during the forty-five-day period, the FDA's approval of the ANDA will become effective immediately. *Id.* 

If the brand-name manufacturer brings such suit within the forty-five day period, the FDA cannot make the ANDA approval effective until after a thirty-month stay, unless a court first decides that the patent is invalid or not infringed by the generic manufacturer's drug – in which case the FDA will follow that determination and approve the ANDA. *Id.* If the patent infringement litigation is not resolved by the conclusion of the thirty-month stay, the FDA's approval of the ANDA becomes effective automatically unless the court handling the infringement litigation alters the length of the stay. *Id.* 

The pediatric exclusivity statute, 21 U.S.C. § 355a, provides that, if a brand-name manufacturer performs certain studies requested by the FDA regarding the effects of the drug on children, the FDA may award the brand-name manufacturer a six-month period of "market exclusivity" following the date of the patent's expiration. During the six-month period, the FDA may not approve any new ANDA, but the statute does not provide for automatic revocation of any already-approved ANDAs. *Id.* § 355a(c)(1)(B)(ii). However, if there is a pending ANDA with a Paragraph IV Certification, the six-month pediatric-exclusivity period only attaches if, "in the patent infringement litigation resulting from the certification[,] the court determines that the patent is valid and would be infringed." *Id.* 

# B. State Drug Substitution Laws

Various state laws seek to encourage competition from generics as well. All fifty states and the District of Columbia have drug substitution laws, which are laws that either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand-name drug unless the prescribing physician expressly directs that the prescription must be dispensed as written. *Namenda II*, 787 F.3d at 644. Drug substitution laws give a preference to generic drugs because generics are generally cheaper than their brand-name counterparts. (Pls.' Count Five 56.1 ¶ 26.)

However, all substitution laws require the generic drug to be "therapeutically equivalent" to the brand-name drug for which it is substituted, and prohibit the substitution of drugs that are not therapeutic equivalents. Unfortunately, not all states define therapeutic equivalence in the same manner. Thirty states and the District of Columbia have adopted the FDA's definition of therapeutic equivalence and only allow generic substitution if the FDA designates the generic as therapeutically equivalent in a publication commonly referred to as the "Orange Book."

Namenda II, 787 F.3d at 645; see N.Y. Educ. Law § 6816–a(1); N.Y. Pub. Health Law

§ 206(1)(o); U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") (37th ed. 2017). Other states take other approaches, such as "develop[ing] formularies that list permissible or impermissible drug substitutes" or "giv[ing] discretion to individual pharmacists as long as the drugs are pharmaceutically equivalent." Namenda II, 787 F.3d at 645 n.9.

The FDA assigns a number of ratings to therapeutically-equivalent drugs. Drugs for which there are no known or suspected bioequivalence problems are assigned ratings of AA, AN, AO, AP, or AT, depending on the dosage form, and drugs for which "actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence" are given the rating AB. U.S. Food & Drug Admin., *Preface to Thirty Seventh Edition*, Orange Book, at xiii. Any of these therapeutically-equivalent ratings would appear to satisfy, for example, New York's requirements for generic substitution. N.Y. Educ. Law § 6816–a(1); N.Y. Pub. Health Law § 206(1)(o)(2).

According to the FDA, two drugs are considered therapeutic equivalents "only if they are pharmaceutical equivalents for which bioequivalence has been demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." U.S. Food & Drug Admin., *Preface to Thirty Seventh Edition*, Orange Book, at vii. Two drugs are considered pharmaceutical equivalents if they "contain the same active ingredient(s), are of the same dosage form, route of administration and are formulated to contain the same amount of active ingredient, and to meet the same or compendial or other applicable standards (i.e., strength, quality, purity, and identity)." *Id.*; see also Namenda II, 787 F.3d at 645. The FDA considers two drugs to be bioequivalent when they display comparable bioavailability ("the rate and extent to which the active ingredient or active

moiety is absorbed from a drug product and becomes available at the site of drug action") when studied under similar experimental conditions. U.S. Food & Drug Admin., *Preface to Thirty Seventh Edition*, Orange Book, at viii.

The requirement that substituted drugs meet therapeutic equivalence standards, although intended to protect patients, allows brand-name drug manufacturers to "game the system" through a practice known as "product hopping." *Namenda II*, 787 F.3d at 645. Before the patent on a brand-name drug expires and its manufacturer loses market share to cheaper generic competitors – the patent cliff – the manufacturer develops a follow-on version of the drug with a later patent expiration date and encourages patients and their physicians to switch to that version. Because the generic version of the follow-on drug is not "therapeutically equivalent" to the original brand-name drug, pharmacies cannot substitute a generic version of the original drug for the follow-on version – even if the pharmacological difference between the original and the follow-on drugs is negligible. *Namenda III*, 2016 WL 4992690, at \*3.

Brand-name drug manufacturers can use a variety of tactics to encourage patients and physicians to convert from the original brand-name drug to the follow-on version prior to the patent cliff. In what has been termed a "soft switch," a manufacturer may aggressively promote and market the follow-on drug to patients and doctors, or may reduce its price compared to the original drug, in order to incentivize voluntary conversions. *Id.* at \*4. In what has been termed a "hard switch" (sometimes called a "forced switch"), a manufacturer may stop selling the original drug prior to the expiration of its patent term, in order to force patients and physicians to switch to the follow-on drug in order to ensure continuity of treatment. *Id.* If, after briefly switching from the original brand-name drug to the follow-on brand-name drug, a patient switches back to

a generic version of the original drug, this process is known as "reverse commuting." *Namenda II*, 787 F.3d at 649.

# III. Factual History

In June 2000, Forest entered into a license and cooperation agreement with the Merz Entities, German pharmaceutical companies, to give Forest the exclusive right to market a memantine-based drug in the United States under the Merz Entities' patent, U.S. Patent No. 5,061,703 (the "'703 Patent"). (Pls.' Count One 56.1 ¶¶ 3-4.) Pursuant to that agreement, Forest developed Namenda IR, a twice-daily immediate-release memantine-based tablet. *Namenda III*, 2016 WL 4992690, at \*2. In December 2002, Forest submitted an NDA to the FDA, seeking approval to market Namenda IR for the treatment of Alzheimer's disease. (Pls.' Count One 56.1 ¶ 5.) The FDA approved that NDA on October 16, 2003, and Forest commercially launched Namenda IR in the United States in January 2004. (*Id.* ¶¶ 6-7.)

Forest then submitted an application to the PTO for a five-year extension to the '703 Patent (originally set to expire on April 11, 2010), to account for the time Forest spent obtaining FDA approval for Namenda IR, as permitted by 35 U.S.C. § 156. (*Id.* ¶ 9-10.) The PTO granted that request in March 2009, extending the term of the '703 Patent until April 11, 2015. (*Id.* ¶ 10.)

In January 2014, Forest sought six months of pediatric exclusivity for Namenda IR from the FDA, pursuant to 21 U.S.C. § 355a, and the FDA granted that request in June 2014. (*Id.* ¶ 11; Defs.' Count One 56.1 ¶ 11 (admitting same); *but see* Defs.' Count Five 56.1 ¶ 13-15 (disputing that Forest "requested" the pediatric exclusivity period).) That six-month exclusivity period ran from the expiration of the term of the '703 Patent on April 11, 2015 to October 11, 2015. (Pls.' Count One 56.1 ¶ 12.)

Namenda IR was the first medication in the United States approved for individuals with moderate or severe forms of Alzheimer's disease and quickly became one of Forest's best-selling

drugs. Namenda II, 787 F.3d at 647. It generated approximately \$1.5 billion in annual sales in 2012 and 2013. Id.

At least seventeen generic drug manufacturers filed ANDAs seeking to market generic versions of Namenda IR. (*See* Solomon Decl. ¶ 2, Dkt. No. 146-11.)<sup>4</sup> At issue in this case are seven of those companies (the "Generic Competitors"): (1) Interpharm Holdings, Inc. and Interpharm, Inc., which were acquired by a wholly-owned subsidiary of Amneal Pharmaceuticals, LLC (collectively, "Amneal"); (2) Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"); (3) Lupin Pharmaceuticals, Inc. ("Lupin"); (4) Mylan Pharmaceuticals, Inc. ("Mylan"); (5) Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); (6) Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and (7) Teva Pharmaceuticals USA, Inc. ("Teva"). (Pls.' Count Five 56.1 ¶ 16.)

In the fall of 2007, each of these seven Generic Competitors submitted its ANDA to the FDA along with a Paragraph IV Certification. (*Id.* ¶¶ 17-20 (Amneal), 31-34 (Dr. Reddy's), 45-48 (Lupin), 59-62 (Mylan), 73-76 (Orchid), 86-89 (Sun), 100-103 (Teva).) Defendants timely brought suits for patent infringement against each Generic Competitor. (*Id.* ¶¶ 21-22 (Amneal), 35-36 (Dr. Reddy's), 49-50 (Lupin), 63-64 (Mylan), 77-78 (Orchid), 90-91 (Sun), 104-105 (Teva).) Between September 2009 and July 2010, Defendants reached settlement agreements with all seven manufacturers. (*Id.* ¶¶ 23 (Amneal), 37 (Dr. Reddy's), 51 (Lupin), 65 (Mylan), 79 (Orchid), 92 (Sun), 106 (Teva).)

Each settlement agreement contained a virtually identical provision that Plaintiffs assert was anticompetitive. In each case, Defendants granted the Generic Competitor a license to begin

<sup>&</sup>lt;sup>4</sup> Many of those generic manufacturers have been named defendants in a related suit before this Court, Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC, No. 15 Civ. 6549, but none is a named defendant in the instant action.

selling a generic version of Namenda IR beginning three months prior to the later of (1) the expiration of the '703 Patent or (2) the end of any pediatric exclusivity period attached to the '703 Patent. (*Id.* ¶¶ 25-26 (Amneal), 39-40 (Dr. Reddy's), 53-54 (Lupin), 67-68 (Mylan), 81-82 (Orchid), 94-95 (Sun), 108-109 (Teva).) This meant that, under the settlements, had Forest not obtained the six-month pediatric exclusivity period under 21 U.S.C. § 355a, the seven Generic Competitors would have been able to begin selling generic versions of Namenda IR on January 11, 2015. However, because the FDA granted Forest the six-month pediatric exclusivity period after the settlement agreements were executed, the Generic Competitors could not begin selling their drugs until July 11, 2015. (*See* Pls.' Count One 56.1 ¶ 13; Defs.' Count One 56.1 ¶ 13.)

In June 2010, Forest obtained approval from the FDA for a second memantine drug, a once-daily extended-release memantine capsule called Namenda XR. *Namenda II*, 787 F.3d at 647. Forest began marketing Namenda XR in July 2013. *Id.* Namenda IR and Namenda XR contain the same active ingredient and have the same therapeutic effect, but Namenda IR is a tablet taken twice a day that releases directly into the bloodstream and Namenda XR is a capsule that is taken once a day and releases gradually. *Id.* Namenda IR and Namenda XR are not, therefore, "therapeutic equivalents" under the FDA's definition of that term, and so cannot be substituted for one another under any drug substitution law that requires substitutes to be certified by the FDA as "therapeutic equivalents." Likewise, generic drugs that are therapeutic equivalents of Namenda IR cannot be substituted for Namenda XR under the same standards. (Pls.' Count One 56.1 ¶ 43-44; Defs.' Count One ¶ 43-44.)

The key non-pharmacological difference between Namenda IR and Namenda XR relates to their patent protection. Namenda XR's period of patent exclusivity does not expire until 2029, while Namenda IR's expired in 2015. *Namenda II*, 787 F.3d at 647.

When Forest brought Namenda XR to market in 2013, it engaged in a variety of soft-switch tactics to encourage patients and physicians to convert from Namenda IR to Namenda XR before Namenda IR went off the patent cliff in 2015. *See id.* at 647-48. Forest priced Namenda XR below Namenda IR. (Defs.' Count One 56.1 ¶ 66.) Forest stopped actively marketing Namenda IR and heavily promoted the benefits of Namenda XR, including its lower price and once-daily dosage. (Pls.' Count One 56.1 ¶ 66-68; Defs.' Count One 56.1 ¶ 66-68.)

The parties disagree about whether Forest's soft-switch tactics were effective. (See Pls.' Count One 56.1 ¶¶ 69-71; Defs.' Count One 56.1 ¶¶ 69-71.) In Namenda I, Judge Sweet concluded that Forest executives were concerned that an insufficient number of patients would switch to Namenda XR before generic versions of Namenda IR entered the market, making a hard switch necessary. Namenda I, 2014 WL 7015198, at \*18.

It is undisputed that, on February 14, 2014, Forest announced (via a press release, notice to the FDA, and letters to physicians and patients) that it would discontinue sales of Namenda IR on August 15, 2014. (Pls.' Count One 56.1 ¶ 80; Defs.' Count One 56.1 ¶ 80.) In June of 2014, Forest announced that, due to manufacturing issues with Namenda XR, it would continue selling Namenda IR through the fall of 2014. (Pls.' Count One 56.1 ¶ 85; Defs.' Count One 56.1 ¶ 86.)

# IV. Procedural History

On September 15, 2014, the New York Attorney General filed an initial complaint against Forest in this court, alleging that the hard switch from Namenda IR to Namenda XR violated federal and state antitrust laws. See Complaint, Namenda I, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 1. Shortly thereafter, the Attorney General sought a preliminary injunction to block the discontinuation of Namenda IR sales. See Mot. for Prelim. Inj., Namenda I, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 27. Judge Sweet held a five-day evidentiary hearing on the preliminary injunction motion, during which time the court heard testimony from twenty-

four witnesses and received over 1,400 exhibits. *Namenda III*, 2016 WL 4992690, at \*6. Based on this evidence, Judge Sweet made 167 factual findings and ultimately concluded that a preliminary injunction should issue. *See Namenda I*, 2014 WL 7015198, at \*4-\*33.

A few of Judge Sweet's key factual findings can be summarized here. Judge Sweet concluded that, prior to the entry of generic versions of Namenda IR, brand-name Namenda IR and Namenda XR were the only memantine therapies available to Alzheimer's patients. *Id.* at \*5. He concluded that all other medications then-approved for the treatment of Alzheimer's disease were acetylcholinesterase inhibitors ("CIs"), which are not considered therapeutic equivalents for memantine-based drugs but instead are considered complements (*i.e.*, memantine and CIs are often prescribed together). *Id.* at \*5, \*14-\*15.

Judge Sweet concluded that, after various soft-switch tactics failed, Forest decided to pursue a hard switch in order to preserve its market share. *Id.* at \*16-\*22. That hard switch began on February 14, 2014, when Forest publicly announced that it would discontinue sales of Namenda IR on August 15, 2014. *Id.* at \*18. Judge Sweet concluded that, for a variety of reasons, patients and physicians were reluctant to switch to Namenda XR absent being forced to do so by a hard switch – for instance, because most Alzheimer's patients are in long-term care facilities and take, on average, nine pills per day, moving from a twice-daily form of Namenda to a once-daily form is not particularly beneficial. *Id.* at \*19. Once converted, however, there was a relatively low risk that patients would reverse commute to generic versions of Namenda IR, because Alzheimer's patients are "especially vulnerable" and physicians are therefore reluctant to change their medications, even if it results in cost savings. *Id.* at \*28-\*31.

Judge Sweet concluded that Forest's hard switch would result in "dramatically higher drug costs for insurers and patients." *Id.* at \*31. He also found that Forest had presented no

evidence of economic harm that would result from continuing sales of Namenda IR until the entry of generic competition – aside, of course, from the "harm" to Forest's bottom line. *Id.* at \*32-\*33.

Judge Sweet ultimately determined that New York had raised "substantial questions" regarding the merits of its antitrust claims because the court concluded that Forest's planned hard switch was anticompetitive, Forest's proposed justifications were pretextual, and any procompetitive effects were outweighed by the anticompetitive impact of the hard switch. *Id.* at \*37-\*41. Because New York also demonstrated the potential for irreparable harm, and equities favored an injunction, Judge Sweet entered the injunction on December 15, 2014. *See* Order, *Namenda I*, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 84. That injunction prevented Forest from halting sales of Namenda IR and required Forest to affirmatively undo the effects of its February 2014 announcement by informing patients and physicians that Namenda IR

In May 2015, the Second Circuit affirmed Judge Sweet's ruling on appeal. Significantly, the Circuit also characterized the hard switch as beginning on February 14, 2014 – the date of Forest's public announcement of a planned withdrawal of Namenda IR – concluding that "announcing the imminent discontinuation of a drug is tantamount to withdrawal." *Namenda II*, 787 F.3d at 648.

Pursuant to this decision, Forest kept Namenda IR on the market through July 2015.

On September 22, 2015, Smith filed its initial complaint in the instant case, alleging largely analogous antitrust claims as presented in the original litigation brought by New York. On December 28, 2015, RDC filed its complaint in a separate action, which was then consolidated with this action and recaptioned on January 26, 2016. (Dkt. No. 65). At least two other antitrust actions have been filed against Forest on the same grounds. See A.F. of L. - A.G.C.

Building Trades Welfare Plan v. Actavis, PLC, No. 15 Civ. 4406; Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC, No. 15 Civ. 6549.

On February 16, 2017, Plaintiffs moved for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134) and for partial summary judgment on Count Five (Dkt. No. 138). On March 16, 2017, Defendants cross-moved for partial summary judgment on Count Five (Dkt. No. 161).

# Applicable Legal Standard

Summary judgment is appropriate where there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-50 (1986). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A dispute concerning material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Aldrich v. Randolph Cent. Sch. Dist., 963 F.2d 520, 523 (2d Cir. 1992) (quoting Anderson, 477 U.S. at 248). A genuine issue for trial exists if, based on the record as a whole, a reasonable jury could find in favor of the nonmovant. See Anderson, 477 U.S. at 248. In making its determination, the Court must resolve all ambiguities and draw all reasonable inferences in favor of the non-movant. See id. at 255.

To defeat summary judgment, it is not sufficient for the nonmoving party to present evidence that is conclusory or speculative, with no basis in fact. See Anderson, 477 U.S. at 249-50. Instead, the nonmoving party must go beyond the pleadings and "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). The nonmoving party must present "specific facts showing that there is a genuine issue for trial." Beard v. Banks, 548 U.S. 521, 529 (2006).

"Summary judgment is designed . . . to flush out those cases that are predestined to result in directed verdict." *Lightfoot v. Union Carbide Corp.*, 110 F.3d 898, 907 (2d Cir. 1997).

#### Discussion

# I. Plaintiffs' Motion for Collateral Estoppel and Partial Summary Judgment on Count One Is Granted in Part and Denied in Part

Plaintiffs seek a partial summary judgment of liability on Count One, which asserts that Forest's February 2014 announcement of the upcoming withdrawal of Namenda IR from the market constituted a violation of Section 2 of the Sherman Act. Plaintiffs argue that Forest's antitrust liability for the February 2014 announcement was already determined in the prior Namenda I and Namenda II litigation and therefore Forest is collaterally estopped from relitigating the issue now. Even though Judge Sweet entered a preliminary injunction in Namenda I, Plaintiffs argue that the Second Circuit treated that injunction as permanent in Namenda II, and, therefore, that decision constitutes a "final judgment" entitled to collateral estoppel effect.

Plaintiffs' motion is granted in part and denied in part. While key facts regarding Forest's violation of Section 2 were previously litigated and are entitled to preclusive effect, Plaintiffs' injury was not a subject of the prior litigation and therefore the Court cannot enter a "partial summary judgment of liability" in Plaintiffs' favor.

# A. Plaintiffs Have Satisfied the Elements of Collateral Estoppel as to Forest's Violation of Section 2

"Collateral estoppel, or issue preclusion, prevents the relitigation of an issue that was raised, litigated, and actually decided by a judgment in a prior proceeding." *Jim Beam Brands Co. v. Beamish & Crawford Ltd.*, 937 F.2d 729, 734 (2d Cir. 1991). In order to establish that an issue was determined in a former adjudication, a party asserting collateral estoppel must establish four things: (1) the issues in the prior proceeding and the current proceeding are identical; (2) the